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No. 92-___

Supreme Court, U.S.
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IN THE
Supreme Court of the United States
OCTOBER TERM, 1992

JANE KING,
Petitioner,

v.

THE COLLAGEN CORPORATION,
Respondent.

On Petition for a Writ of Certiorari to the United States Court of Appeals for the First Circuit

PETITION FOR A WRIT OF CERTIORARI

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QUESTION PRESENTED

Whether a provision of the Medical Device Amendments ("MDA") to the Food, Drug and Cosmetic Act, that bars states from "establishing or continuing in effect" device requirements that are "different from, or in addition to" a requirement under the MDA, preempts all state-law damage claims against a manufacturer of a medical device approved for marketing by the Food and Drug Administration ("FDA") where:

> (1) there are no specific federal regulatory requirements for the device in question that coincide with petitioner's state law claims, and (2) the FDA's own view is that the MDA does not preempt damage claims.

PARTIES TO THE PROCEEDINGS

In addition to petitioner Jane King and respondent Collagen Corporation, who appeared as appellant and appellee, respectively, in the court of appeals, the Association of Trial Lawyers of America and the Health Industry Manufacturers Association appeared as *amici curiae* in the court of appeals.

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In The

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No. 92-___

JANE KING,

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PETITION FOR A WRIT OF CERTIORARI

OPINIONS BELOW

The opinion of the United States Court of Appeals for the First Circuit is reported at 983 F.2d 1130 (1993), and is reproduced in the appendix at 1a-21a. The unreported decision of the United States District Court for the District of Massachusetts is reproduced in the appendix at 22a-23a.

JURISDICTION

The judgment of the court of appeals was entered on January 15, 1993. Petitioner filed a timely petition for rehearing on January 29, 1993, which was denied by the court of appeals on February 3, 1993 (24a). On April 26, 1993, Justice Souter granted petitioner's application for an extension of time to file this petition for a writ of certiorari up to and including June 23, 1993. This Court has jurisdiction under 28 U.S.C. § 1254(1).

STATUTORY PROVISION INVOLVED

21 U.S.C. § 360k provides:

State and local requirements respecting devices

(a) General rule

Except as provided in subsection (b) of this

section, no State or political subdivision of a State may establish or continue in effect with respect to a device intended for human use any requirement--

(1) which is different from, or in addition to, any requirement applicable under this chapter to the device, and

(2) which relates to the safety or effectiveness of the device or to any other matter included in a requirement applicable to the device under this chapter.

(b) Exempt requirements

Upon application of a State or a political subdivision thereof, the Secretary may, by regulation promulgated after notice and opportunity for an oral hearing, exempt from subsection (a) of this section, under such conditions as may be prescribed in such regulation, a requirement of such State or political subdivision applicable to a device intended for human use if--

(1) the requirement is more stringent than a requirement under this chapter which would be applicable to the device if an exemption were not in effect under this subsection; or

(2) the requirement--

(A) is required by compelling local conditions, and

(B) compliance with the requirement would not cause the device to be in violation of any applicable requirement under this chapter.

REGULATORY PROVISION INVOLVED

21 C.F.R. § 808.1(d) provides in part:

> State or local requirements are preempted only when the Food and Drug Administration has established specific counterpart regulations or there are other specific requirements applicable to a particular device under the act, thereby making any existing divergent State or local requirements applicable to the device different from, or in addition to, the specific Food and Drug Administration requirements. There are other State or local requirements that affect devices that are not preempted by section 521(a) of the act [21 U.S.C. § 360k(a)] because they are not "requirements applicable to a device" within the meaning of section 521(a) of the act. The following are examples of State or local requirements that are not regarded as preempted by section 521 of the act:
>
> (1) Section 521(a) does not preempt State or local requirements of general applicability where the purpose of the requirement relates either to other products in addition to devices (e.g., requirements such as general electrical codes, and the Uniform Commercial Code (warranty of fitness)), or to unfair trade practices in which the requirements are not limited to devices. ...

STATEMENT OF THE CASE

In what the former Chief Counsel to the Food and Drug Administration ("FDA") has called "probably the single most important case to the medical-device industry in American history,"[1] the court of appeals has held that the Medical Device Amendments ("MDA") to the Food, Drug and Cosmetic Act, 21 U.S.C. § 301 *et seq.*, preempt all damages claim against a medical device manufacturer on the ground that Congress intended the

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[1] Edward Felsenthal & Lee Berton, *FDA Approval Shields Firms in Injury Suits*, Wall St. J., Jan. 21, 1993, at B1 (quoting Peter Hutt, former FDA Chief Counsel).

FDA's marketing approval for the device to insulate the manufacturer from state-law liability. The court of appeals erred because the MDA's express preemption language, 21 U.S.C. § 360k(a), applies only to situations where there is a counterpart federal regulation or a provision of the MDA specifically applicable to a particular device, and because that language applies only to state and local positive enactments, not damage claims. These conclusions are in accord with regulations of the FDA, the federal agency specifically charged with implementing and interpreting the MDA.

Furthermore, as the court of appeals acknowledged (18a), the decision below posits that Congress intended to leave injured patients without any remedy against the manufacturers of Class III medical devices -- devices that are the most likely to cause serious injury to consumers. *See* 21 U.S.C. § 360c(a)(1)(C). Under the First Circuit's reasoning, Congress deliberately intended to displace the tort system and deprive consumers of a remedy, regardless of the severity of the injury or the theory of liability alleged, including the manufacturer's fraud in obtaining device approval from the FDA. The First Circuit came to this conclusion, even though Congress did not say a word about preempting common law actions and did not provide an alternative compensation system. Review is also warranted because the lower federal courts and state courts are deeply divided over the preemptive scope of the MDA, including the precise issue presented in this petition, and because the decision of the court of appeals is at odds with this Court's Supremacy Clause jurisprudence, particularly with the Court's recent decision in *Cipollone v. Liggett Group, Inc.*, 112 S. Ct. 2608 (1992).

1. *Facts and Procedural Background.* In May 1987, petitioner Jane King was injected with a test dose of Zyderm, a medical device manufactured by respondent Collagen Corporation. Zyderm treatment consists of injecting processed cow tissue under the skin, which is supposed to correct wrinkles and other skin deformities by bolstering the skin from below (2a). Shortly after receiving the test dose, but before undergoing the full treatment, petitioner began suffering from extreme weakness and pain in her muscle joints, particularly in her legs, arms, and neck (3a).

Compl. ¶ 6 (A00007).[2] Petitioner maintained that the test dose of Zyderm caused her to suffer from polymyositis or dermatomyositis ("DM/PM"), autoimmune diseases that cause the immune system to attack skin and muscle tissue as if they were foreign substances, rendering petitioner permanently and totally disabled. *Id.* ¶ 7.

In October 1990, petitioner filed her complaint in Massachusetts Superior Court, alleging that Zyderm was labeled, promoted, and sold with inadequate warnings of possible adverse reactions and no warnings about autoimmune diseases such as PM/DM. *Id.* ¶¶ 10-11 (A00008). Petitioner also maintained that respondent knew or should have known that Zyderm likely caused DM/PM, but nevertheless failed to warn her, and further engaged in an active campaign to suppress the facts, blame the disease on other causes, and to prevent discovery of the risks associated with Zyderm. *Id.* ¶¶ 12-13. The alleged campaign of fraud and misrepresentation extended to efforts to deceive patients, their doctors, and the FDA during the device approval process. Amd. Compl. ¶¶ 9, 12 (A00029, A00030).[3]

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[2] References beginning with "A" refer to respondent's Record Appendix filed in the court of appeals.

[3] Respondent moved for summary judgment on preemption grounds, and thus neither the court nor the jury heard petitioner's evidence (A00033). Petitioner maintained that respondent failed to warn of DM/PM, although it could have done so (A00464), and that respondent knew of the DM/PM association for many years but did not specifically warn of it until the FDA and others unearthed the information (A00483). Among other things, petitioner specifically maintained that respondent withheld information by failing to file with the FDA legally-required reports of adverse reactions (A00479), by publishing misleading pamphlets and "Dear Doctor" letters (*id.*), and by falsely trumpeting the significance and extent of FDA approval of its product (A00483). Petitioner also proffered expert testimony that the original 1981 FDA marketing approval for Zyderm was fraudulently obtained because of the way in which clinical data was presented and the withholding of pertinent information (A00491-A00514). *See also* A00515-00520 (describing FDA seizure of mislabeled Zyderm, and noting that, upon examination of more complete data, FDA took position that there may be a significant association between use of Zyderm and occurrence of PM/DM); Committee on Government Operations of the U.S. House of Representatives, *Is the FDA Protecting Consumers From Dangerous Off-Label Uses of Medical Drugs and Devices?* 22-28, 41 (GPO Nov. 19, 1992)(concluding that respondent

(continued...)

The original complaint alleged three counts. Count I set out respondent's negligence in failing to adequately test and manufacture Zyderm and in marketing the product, Count II claimed that respondent breached an implied warranty of merchantability and/or unlawfully sold a defective or dangerous product, and Count III alleged that petitioner's injuries were a result of respondent's deceit or fraud (A00009). Petitioner's Amended Complaint, filed on January 23, 1992 (Docket Entry 42, A00006), reorganized these allegations as claims for strict liability, breach of warranty, negligence, product misbranding and mislabeling, misrepresentation, failure to warn, and fraud (A00027-A00030).

On November 9, 1990, respondent removed the case to the United States District Court for the District of Massachusetts on the basis of diversity of citizenship (A00013), and filed an answer (A00015). After both parties were afforded discovery, respondent moved for summary judgment on the ground that petitioner's claims were preempted by the MDA (A00033), specifically by the FDA's 1981 decision to allow Zyderm to be marketed. In a two-page memorandum opinion (22a-23a), Judge A. David Mazzone granted respondent's motion for summary judgment, relying solely on a Texas case involving Zyderm in which summary judgment was granted to respondent on the basis of the FDA's marketing approval.[4] Thereafter, petitioner moved the district court to reconsider its decision. The court declined to do so because, by that time, the court of appeals had taken jurisdiction of the case, but Judge Mazzone noted that "[i]f I had authority, I would grant this motion to reconsider." Appellant's [First Circuit] Excerpts of Record, Ex. G.

2. *Decision of the Court of Appeals.*

The court of appeals affirmed in two separate opinions, one written by Judge Juan R. Tourrella and the other, labelled a

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[3](...continued)
mislabeled and misrepresented Zyderm and failed to make necessary reports to FDA, and discussing potential relationship between PM/DM and Zyderm).

[4] *See Stamps v. Collagen Corporation*, No. H-90-2242 (S.D. Tex. Oct. 11, 1991)(A00530-A00534), *aff'd*, 984 F.2d 1416 (5th Cir. 1993). A petition for a writ of certiorari will be filed in *Stamps* on or about June 16, 1993.

"concurring" opinion, but representing the panel majority, written by Senior Judge Bailey Aldrich, joined by Senior Judge Levin H. Campbell. We review each opinion in turn.

After briefly discussing the history and uses of Zyderm, Judge Tourrella turned to the MDA's pre-market approval process, noting that Zyderm was placed in Class III "for medical devices which are too dangerous or unknown to permit less regulation" (2a). Under that process, respondent was required to submit proposed labeling, testing data, and other information deemed pertinent by the FDA (*id.*), and the Agency retained the power to conduct various forms of post-market surveillance (3a), as it does with all devices.

After Zyderm was approved by the FDA, up to when petitioner fell ill after receiving her Zyderm injection in 1987, Judge Tourrella noted, use of the device was only contraindicated for users with a personal history of autoimmune disease (*id.*). By 1991, that contraindication had been removed from the labeling, but the FDA required in that year that respondent specifically warn that some patients, such as petitioner, had suffered an autoimmune response after Zyderm use.

Judge Tourrella reviewed the causes of action alleged in petitioner's amended complaint, and then considered what he viewed as the relevant legal background.[5] After reciting basic preemption principles (5a-6a), Judge Tourrella considered the MDA's preemption language, 21 U.S.C. § 360k(a), which provides that

> [N]o State ... may establish or continue in effect with respect to a device intended for human use any requirement (1) which is different from, or in addition to, any requirement applicable under this chapter to the device, and (2) which relates to the safety or effectiveness of the device or to any other matter included in a requirement applicable

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[5] The causes of action alleged in the amended complaint are discussed *supra* at 5-6. Although there was a dispute as to whether the amended complaint, rather than the original complaint, was the operative legal document, both panel opinions resolved that dispute in favor of the amended complaint (3a n.1, 14a), and, therefore, we look to that pleading as well.

to a device under this chapter.

Judge Tourrella then turned "for guidance" (7a) to the FDA's regulations on MDA preemption, 21 C.F.R. § 808.1, which recognize that preemption occurs only where the FDA has issued regulations, or the MDA itself creates requirements, specific to a particular device and a state has established different or additional statutory or regulatory requirements on the same subject matter. He then stated that federal law imposed requirements "on Zyderm related to labeling, design, manufacturing and other aspects of the device ... (7a)," without explaining the specific FDA requirements to which he was referring (8a), and without analyzing the FDA's regulations or regulatory commentary concerning the scope of MDA preemption. "Armed with this understanding" of the MDA's preemption provision (*id.*), 21 U.S.C. § 360k(a), Judge Tourrella analyzed the viability of petitioner's claims, rejecting each of them on preemption grounds.

As to strict liability, Judge Tourrella stated that, because the general purpose of MDA device approval is to ensure reasonable safety for users, petitioner's claim was preempted because it would impose requirements "related to ... safety and effectiveness" (8a) and require respondent to redesign its product. He did not point, however, to any specific FDA regulations or approval requirements relating to Zyderm design that conflicted with the strict liability claim.

Petitioner's implied warranty of merchantability claim was preempted because it arose by operation of state contract law, and thus would impose an additional requirement on respondent (10a). Here, again, Judge Tourrella did not explain what applicable FDA requirement was in conflict with petitioner's cause of action (*id.*). Similarly, Judge Tourrella rejected the negligence claims with respect to design, manufacture, sale, and marketing of Zyderm, noting that Class III devices are subject to regulation in those general areas, but not pointing to any specific FDA regulation of collagen implants on those particular matters (*id.*).

Turning to petitioner's misbranding claim (*id.*), Judge Tourrella maintained that it, too, was preempted because respondent's labeling accurately described the product, notwithstanding petitioner's allegations that the labeling understated Zyderm's risks and respondent's obligation to insure that its

labeling was neither false or misleading (*id.*, *citing* 21 U.S.C. § 352(a)). Similarly, in Judge Tourrella's view, the failure to warn and misrepresentation claims were preempted because they would have required that respondent's label read differently from the FDA-approved version, despite respondent's freedom to add safety warnings without FDA approval (11a), *see* 21 C.F.R. § 814.39(d)(1), and the fact that the misrepresentation claim relied on allegations of deceptive labeling and promotion of the product to petitioner's physician, not simply a duty to warn prospective users.

Finally, as to the fraud claim, Judge Tourrella held that, because petitioner's claim was, in his view, solely one under a Massachusetts statute requiring privity between buyer and seller, it was barred as a matter of state law (11a). However, he stated alternatively that the fraud count was preempted because it was a disguised failure to warn claim (*id.*), without addressing petitioner's allegation of respondent's fraud on the FDA in the marketing and approval of Zyderm.

After reviewing petitioner's causes of action and the MDA's legislative history (12a-16a), Judge Aldrich, joined by Judge Campbell, began with 21 U.S.C. § 360e(c)(1), the part of the MDA that describes the contents of a Class III pre-market approval application (16a-17a). In particular, Judge Aldrich looked to § 360e(c)(1)(F), which requires the applicant to submit proposed labeling to the FDA. Because the MDA requires that "labels be reviewed by the FDA," he said, "preemption ... is unavoidable ..." (18a). Judge Aldrich believed that this provision was critical, because, except for fraud, all of petitioner's causes of action -- such as misrepresentation, breach of implied warranty, and negligent design and testing -- were failure to warn claims (13a). This was so, in Judge Aldrich's view, because, had respondent warned petitioner that Zyderm might cause PM/DM, petitioner "would have no claim under any of these headings" (13a).

Judge Aldrich also noted that, under 21 C.F.R. § 814.39(d)(1), respondent could have changed its labeling to add warnings without FDA approval, but held that provision of no significance since it is not mandatory (18a). He did not explain, however, why a state warning claim to enhance safety under such

circumstances would be "different from or in addition to" the federal scheme. The opinion also acknowledged petitioner's argument that the FDA's preemption regulations, 21 C.F.R. § 808.1(d), would allow her claims to go forward, but dismissed that point by stating that "[w]hen a statute is clear the agency interpretation must give way" (18a).

Finally, Judge Aldrich addressed the "more troublesome issue" of fraud (*id.*), particularly as it applied to petitioner's allegation that Zyderm's approval itself was procured through deception of the FDA (19a). While acknowledging a conflict with *Hurley v. Lederle Laboratories Division of American Cyanamid Co.*, 863 F.2d 1173 (5th Cir. 1988), he held that whether there has been fraud on the FDA was a determination to be made by the Agency, not a jury (20a). Moreover, in Judge Aldrich's view, petitioner's claim of misrepresentation based on statements made to the public and petitioner's physician was also preempted because those statements were "approved by the FDA ..." (21a n.8). Judge Aldrich did not refer, however, to a particular substantive federal requirement pertaining to Zyderm that conflicted with petitioner's state-law fraud or misrepresentation claims.

REASONS FOR GRANTING THE WRIT

The FDA -- the agency charged by Congress with implementing and interpreting the MDA -- has consistently maintained that the preemptive effect of 21 U.S.C. § 360k(a) is confined in two related respects. First, it believes that § 360k(a) does not oust state law unless the FDA has established, or the MDA itself contains, specific requirements with respect to a particular device, and the state has established specific different or additional requirements applicable to the same aspect of that particular device. *See, e.g.*, 21 C.F.R. § 808.1(d). Second, the FDA has concluded that § 360k(a) does not apply at all to duties created under state tort and contract law that are intended to compensate injured consumers, because those duties are of "general applicability where the purpose of the requirement relates ... to other products in addition to devices ... ." *Id.* § 808.1(d)(1).

In this case, the First Circuit issued two opinions, one which purports to rely on the FDA's views (7a), but fails even to cite the most relevant of those views, and the other which dismisses the FDA's interpretations in one sentence (18a),

apparently on the ground that they are inconsistent with the statute. As a result, the First Circuit's ruling conflicts with the language of the MDA, the FDA's interpretation of that language, decisions of other state and federal courts, and this Court's ruling in *Cipollone*. In addition, the court of appeals' reasoning sweeps so broadly that not only petitioner, but *all* patients who are injured by Class III medical devices -- devices that are the most dangerous and likely to cause injury -- would be left without a remedy.

A. Review Should be Granted Because the Ruling of the Court of Appeals is Inconsistent with (1) the Language of the MDA and the Authoritative Regulations of the FDA, (2) Decisions of Other Federal and State Courts, and (3) This Court's Ruling in *Cipollone*.

Before turning to the MDA's preemption provision, it is important to review four bedrock principles applicable to this case that were largely overlooked by the court of appeals. First, because of the importance of preserving our delicate state-federal balance, *Hillsborough County, Fla. v. Automated Medical Laboratories, Inc.*, 471 U.S. 707, 713 (1985), there is a strong presumption against preemption that may only be overcome by "clear and manifest" Congressional intent to oust state and local law. *See Wisconsin Public Intervenor v. Mortier*, 111 S. Ct. 2476, 2482, 2485 (1991). Second, this powerful presumption is even stronger where, as here, preemption would displace the historic power of the state to protect the health and safety of its citizenry. *Rice v. Sante Fe Elevator Corp.*, 331 U.S. 218, 230 (1947). Third, where a finding of preemption of common law claims would leave injured consumers without *any* state *or* federal remedy, as concededly is the case here (18a), this Court ascribes preemptive intent to Congress only in the most compelling circumstances. *Silkwood v. Kerr-McGee Corp.*, 464 U.S. 238, 251 (1984). Finally, in the preemption context, as in others, the views of the agency charged with administering the statutory scheme are entitled to deference, *Hillsborough County*, 471 U.S. at 714, which is important here because, as we explain below, the FDA's views of MDA preemption are flatly at odds with the result reached by the court of appeals.

1. *The Language of the MDA and the FDA's Regulations.* With these principles in mind, we turn to the MDA's

preemption provision:

> [N]o State ... may establish or continue in effect with respect to a device intended for human use any requirement (1) which is different from, or in addition to, any requirement applicable under this chapter to the device, and (2) which relates to the safety or effectiveness of the device or to any other matter included in a requirement applicable to a device under this chapter.

21 U.S.C. § 360k(a).

This language does not preempt all state-imposed forms of liability that relate to the safety and effectiveness of a device subject to the MDA, as, in essence, the court of appeals held. Rather, state device requirements are preempted only if they are requirements "with respect to a device" and are "different from, or in addition to" pre-existing federal requirements that concern that particular device's safety and effectiveness. Thus, even if § 360k(a) applies to common law damage actions, which petitioner and the FDA dispute (*see infra* Part B), petitioner's claims, based on the inadequate design and testing of Zyderm, the manufacturer's failure to warn, breach of implied warranty, misrepresentation, and fraud, would be preempted under § 360k(a) only if there are federal requirements imposed upon collagen implants regarding those subject matters. Here, however, there are no warnings required by regulation, nor are there specific regulations or statutory provisions requiring that collagen implants be designed, manufactured, sold, or tested in a particular manner, so there are no federal "requirements" that could preempt petitioner's claims.

The First Circuit nonetheless held that, because respondent had obtained approval for Zyderm under the MDA's pre-market approval ("PMA") procedures, 21 U.S.C. § 360e, *see* 21 C.F.R. pt. 814, *any* claim concerning "safety or effectiveness" against the manufacturer of an approved device was preempted. In doing so, the court relied on the purported comprehensiveness of these procedures (14a, 16a), especially the need for the applicant to submit its proposed labelling with its PMA application (18a), and the importance of encouraging the marketing of devices (15a). The court failed, however, to square its ruling with the MDA's preemption provision and the FDA regulations promulgated

thereunder. In particular, none of the statutory or regulatory provisions for approval of Class III devices are device-specific in character, and, as we have noted, none require collagen implants to conform to any specifications or to be labeled in a certain fashion. The only statutes and regulations cited by the court of appeals concern *general* procedural requirements applicable to *all* Class III devices, not "specific counterpart regulations or ... specific requirements applicable to a particular device under the" MDA. 21 C.F.R. § 808.1(d).[6]

On this score, the First Circuit's decision conflicts with *Larsen v. Pacesetter Systems, Inc.*, 837 P.2d 1273 (Haw. 1992). There, the Hawaii Supreme Court, in a case concerning defective heart pacemaker devices -- class III devices, *see, e.g.*, 21 C.F.R. §§ 870.3600-.3620 -- expressly rejected the manufacturer's argument that the PMA process preempted the plaintiff's implied warranty claim, because "the statutes and regulations governing pre-market approval set forth general procedural requirements and, therefore do not trigger preemption under [21 C.F.R.] § 808.1(b)." *Id.* at 1282.[7]

Consistent with *Larsen*, petitioner's view of MDA preemption is precisely the one taken by the FDA in regulations

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[6] As we have noted, Class III devices are those that must go through the PMA process because they are the most likely to cause patients serious harm. 21 U.S.C. § 360c(a)(1)(C). However, Class III devices that were marketed prior to the MDA's 1976 effective date or which are deemed "substantially equivalent" to pre-MDA devices need not go through the full PMA process until the FDA issues a regulation calling for the submission of PMA applications. *Id.* § 360c(f)(1)(A). The FDA does, however, require the submission of proposed labeling, among other information, to make its substantial equivalence findings, *see id.* § 360c(i)(3); 21 C.F.R. § 807.87(e), as well as clinical data in some cases similar to data filed with PMAs. *See* H.R. Rep. No. 808, 101st Cong., 2d Sess. 14 (1990), *reprinted in* 1990 U.S.C.C.A.N. 6305, 6307.

[7] *Larsen* held secondarily that, since the relevant devices entered the market based on a finding of substantial equivalence, preemption was also inappropriate. 837 P.2d at 1282. Under the First Circuit's approach, which placed chief reliance on the fact that the FDA reviewed respondent's proposed labeling (18a), *Larsen*'s secondary rationale would also trigger a finding of preemption, because the applicant must submit proposed labeling in substantial equivalence cases, as well as in cases involving full PMA submissions. *See* 21 C.F.R. § 807.87(e).

defining what types of state and local authority are and are not preempted under 21 U.S.C. § 360k(a):

> State or local requirements are preempted *only where the Food and Drug Administration has established specific counterpart regulations or there are other specific requirements applicable to a particular device under the act*, thereby making any existing state or local requirement different from, or in addition to, the specific Food and Drug Administration requirements.

21 C.F.R. § 808.1(d)(emphasis added).

In promulgating these regulations, FDA explained why the preemptive effect of § 360k(a) must be interpreted narrowly. The Agency looked first to the words chosen by Congress, discussing the language dictating that there be a federal *requirement* with respect to *a device*, and found that device-specific federal rules must first be in place before preemption can occur. 43 Fed. Reg. 18,661, 18,662 (May 2, 1978)(highlighting italicized statutory language). The FDA further explained:

> Thus, from a plain reading of section 521 of the act it is clear that the scope of preemption is limited to instances where there are specific FDA requirements applicable to a particular device or class of devices. ... [A] prime example is the preemption of divergent State or local requirements relating to hearing aid labeling ..., which occurred when the new FDA hearing aid regulations [concerning labeling and conditions for sale] took effect.... [O]nly requirements relating to labeling and conditions for sale were preempted, not all State or local requirements regulating other facets of hearing-aid distribution. *Id*.

This insistence upon device-specific FDA requirements for the same subject matter regulated by the state -- what the FDA refers to as the need for "specific counterpart" requirements -- is found throughout the FDA's regulations. For instance, the MDA does not preempt state or local registration or certification schemes for medical professionals simply because they "administer,

dispense, or sell devices." 21 C.F.R. § 808.1(d)(3). If, however, the FDA exercises its authority under the MDA to restrict the use of certain devices to particular health professionals, *see* 21 U.S.C. §§ 360j(e),(g), then the federal requirements control, but only to the extent that they actually conflict with state and local regulations. 21 C.F.R. § 808.1(d)(3). And, of particular relevance here, the FDA has made absolutely clear that 21 U.S.C. § 360k(a)

> does not preempt State or local requirements of general applicability where the purpose of the requirement relates ... to other products in addition to devices (e.g., requirements such as ... *the Uniform Commercial Code (warranty of fitness)) or to unfair trade practices in which the requirements are not limited to devices* ....

21 C.F.R. § 808.1(d)(1)(emphasis added). Here, of course, petitioner's causes of action are all based on common law duties of "general applicability," and thus her implied warranty, fraud, and misrepresentations claims are specifically preserved by the FDA regulation. *See infra* Part B.[8]

2. *Conflicting Case Law.* In addition to *Larsen*, much of the case law rejects the First Circuit's approach -- that the marketing approval of a device standing alone may have preemptive effect. Rather, the cases support the FDA's view that the scope of MDA preemption is narrow and occurs only where the Agency has device-specific regulations, or where the Act itself imposes device-specific specifications in the precise area in which the state or locality is attempting to regulate.

Precedent concerning hearing aids -- a subject of early FDA regulation under the MDA -- cannot be squared with the First Circuit's approach. For example, in *Smith v. Pingree*, 651 F.2d

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[8] Petitioner's implied warranty of merchantability claim is the same type of warranty provided under the Uniform Commercial Code, Mass. Gen. Laws, ch. 106, § 2-314, and thus is expressly allowed by the FDA's regulations. Similarly, petitioner's claims for fraud and misrepresentation are directly analogous to the unfair trade practices act claims preserved in the FDA's regulation, because those acts codify and expand the common law causes of action for fraud and deceit. *See* Mass. Gen. Laws, ch. 93A, § 2.

1021 (5th Cir. Unit B 1981), the court held that a Florida law regulating the sale of hearing aids was not preempted, even though the FDA had the power to regulate in that same area and had in fact issued certain requirements with respect to hearing aids. The court held that 21 C.F.R. § 801.420(c), which requires sellers of hearing aids to provide information to prospective purchasers to promote consumer safety and improve the quality of the hearing aid, did not preempt Florida's requirement that sellers provide each purchaser with certain consumer information (*e.g.*, seller's business address, serial number of hearing aid, whether the hearing aid was new, used, or rebuilt, where consumer complaints could be filed, etc.). *Smith*, 651 F.2d at 1024-25. Contrasting the FDA's effort to protect the safety of the user with Florida's efforts to safeguard consumers' rights after purchase, the court found "that the Florida statute does not relate 'to a matter included in a federal requirement applicable to a device'" and, therefore, was not preempted by the federal regulation. *Id.* at 1025. Similarly, the court affirmed Florida's authority to require a disclaimer both on the packaging containing the hearing aid and the customer's itemized receipt concerning a hearing aid's inability to restore hearing loss, even though there existed an FDA requirement that the disclaimer appear on a brochure accompanying the hearing aid. Because the federal regulation dealt with an informational brochure, not packaging, there was no federal regulatory requirement which could be said to preempt Florida law. *Id.*

In *New Jersey Guild of Hearing Aid Dispensers v. Long*, 384 A.2d 795 (N.J. 1978), the New Jersey Supreme Court considered numerous state regulations designed to protect hearing aid consumers, similar to, but in some ways more comprehensive than, those at issue in *Pingree*. The regulations banned the use of certain misleading professional titles, required price lists for hearing aids, barred non-consensual home visits by sellers, set price guidelines, and the like. After discussing general preemption principles, 384 A.2d at 808, the court considered the FDA's proposed regulations concerning the MDA's preemptive effect, now codified at 21 C.F.R. § 808.1. In light of the "fundamental maxim that the opinion as to the construction of a regulatory statute of the expert administrative agency charged with the enforcement of that statute is entitled to great weight," 384 A.2d at 810, the court chose to "follow the FDA's reasonable

interpretation" of § 360k(a) because there "are no 'compelling indications that it is wrong.'" *Id.* (*quoting Red Lion Broadcasting Co. v. F.C.C.*, 395 U.S. 367, 381 (1969)).[9]

Cases concerning FDA regulation of tampons are also at odds with the ruling below. For instance, in *Bejarano v. International Playtex, Inc.*, 750 F. Supp. 443 (D. Idaho 1990), the court considered a tampon manufacturer's argument that the claims of a toxic shock syndrome ("TSS") victim were preempted both by the MDA itself and by FDA regulations directing tampon manufacturers to place specific warnings on tampon packages and package inserts. *See* 21 C.F.R. § 801.430. The plaintiff claimed that her TSS was attributable to the manufacturer's breach of the duty to warn and the improper design and construction of the tampon. 750 F. Supp. at 445. The court held that the duty-to-warn claim was preempted, but that the design and construction claims were not, because federal law did not dictate a specific design or construction, only that a specific warning be given.[10]

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[9] Under *Chevron U.S.A., Inc. v. Natural Resources Defense Council, Inc.*, 467 U.S. 837, 843 (1984), the FDA's final regulations would be entitled to even greater respect than was accorded to the proposed regulations in *New Jersey Guild*. *See Hillsborough County, Fla. v. Automated Medical Laboratories, Inc.*, 471 U.S. 707, 714 (1985)(applying *Chevron* to defer to FDA's position narrowly construing preemption).

[10] The Hawaii Supreme Court, which, as we have noted, has rejected the notion that pre-market approval for a class III device preempts state claims, *Larsen v. Pacesetter Systems, Inc.*, 837 P.2d 1273, 1280-82 (1992), relied heavily on *Bejarano* and other tampon cases in holding that the PMA regulations were simply too general to warrant preemption. *Id.* at 1281-82 (*citing, e.g., Moore v. Kimberly-Clark Corp.*, 867 F.2d 243, 247 (5th Cir. 1989)). Indeed, the conclusion that the FDA's tampon labeling requirements preempt only state duty-to-warn claims, and leave other claims unaffected, has been followed by many courts. *E.g., Moore, supra; Krause v. Kimberly-Clark Corp.*, 749 F. Supp. 164, 169 (W.D. Mich. 1990); *Rinehart v. Int'l Playtex, Inc.*, 688 F. Supp. 475 (S.D. Ind. 1988). However, like the court below, a few courts have found broader preemption under the MDA. *See, e.g., Stamps v. Collagen Corp.*, 984 F.2d 1416 (5th Cir. 1993)(holding PMA preempts common law claims, despite prior ruling in *Moore*); *Desmarais v. Dow Corning Corp.*, 712 F. Supp. 13 (D. Conn. 1989)(duty to warn claims for *all* prescription devices marketed after passage of MDA preempted pursuant to general labelling regulations); *Lavetter v. Int'l*

(continued...)

In sum, the court of appeals based its preemption holding on general procedural requirements for FDA device approval, rather than on any "special features warranting preemption." *Hillsborough County*, 471 U.S. at 719. That approach cannot be squared with *Larsen* and the majority of the hearing aid and tampon cases under which claims for defective design, implied warranty, and fraud were held not to be preempted despite comprehensive FDA regulation.

3. *Cipollone.* The decision below is also inconsistent with the narrow approach to preemption taken by this Court in *Cipollone v. Liggett Group, Inc.*, 112 S. Ct. 2608 (1992). There, the Court considered the preemptive effect of § 5(b) of the Public Health Cigarette Smoking Act of 1969, on a variety of damage claims raised by a cigarette smoker who had died from using the defendant's product. Section 5(b) provided that "no requirement or prohibition based on smoking and health shall be imposed under State law with respect to the advertising or promotion of any cigarettes the packages of which are labeled in conformity with the provisions of this Act." *Id.* at 2617. Section 4 of the Act mandated that a specific warning be placed on all cigarette packaging and advertising. *Id.* at 2616.

The four-Justice *Cipollone* plurality rejected the manufacturer's argument that all of the plaintiff's damage claims were preempted, and instead analyzed each cause of action in light of § 5(b)'s language and purposes. Because Cipollone's duty-to-warn claims would create state-imposed tort liability on the basis of a failure to give a warning over and above *the specific warnings required by Congress*, those claims were preempted. *Id.* at 2621.

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[10](...continued)
Playtex, Inc., 706 F. Supp. 722, 723 (D. Ariz. 1988)(preempting entire claim, but unclear whether plaintiff made claims other than duty to warn); *National Women's Health Network, Inc. v. A.H. Robins Co., Inc.*, 545 F. Supp. 1177, 1181 (D. Mass. 1982)(preempting state law claim for warning to users of Dalkon Shield on ground that federal interest in medical devices is "dominant" and "pervasive," without citation or analysis of statutory or regulatory provisions on preemption). We note that the FDA rejected the broad preemption holding in *National Women's Health* in an advisory opinion holding that the MDA was not intended to preempt common law remedies at all (*see* 25a-26a, discussed *infra* 22).

But other claims -- fraudulent misrepresentation, conspiracy to misrepresent or conceal facts, and breach of warranty -- were not preempted because, while they dealt with "smoking and health" in some sense, they were grounded legally on either a general tort duty not to deceive or on a contractual relationship between the parties. *Id.* at 2623-24 & n.27.

Under *Cipollone*, then, the duty-to-warn claims were preempted precisely because mandatory federal warnings were the centerpiece of a federal law and of its preemption provision; in the tampon cases (discussed *supra* at 17 & n.10), such claims were held preempted for the essentially same reason -- that mandatory warnings were the subject of a specific federal requirement. But also for the same reason, the tampon cases, consistent with *Cipollone*, generally hold that design defect claims are not preempted, because tampon design is not the subject of a federal requirement. Put another way, if the FDA had promulgated mandatory labeling for all collagen implants, as it has for tampons and hearing aids, then *Cipollone* might arguably require preemption of petitioner's failure-to-warn claims, but no others.[11]

Cipollone's holding that fraud-based claims were not preempted is particularly noteworthy, because the general tort duty not to deceive, to which the Court referred in *Cipollone*, is the same duty upon which petitioner relies in her fraud and misrepresentation counts. The First Circuit's response -- that because the only fraud alleged by petitioner was perpetrated on the FDA in approving and labeling the device, it was up to the FDA, not the tort system, to redress the problem -- is faulty for two reasons. First, a jury award based on fraud on the FDA does not, under § 360k(a), establish a "requirement" with respect to Zyderm "different from, or in addition to" a pre-existing MDA requirement on that subject matter. Rather, as in *Cipollone*, the cause of action is based on a general duty not to deceive, and has no basis in any particular MDA requirement. Second, petitioner's claims extend beyond fraud on the FDA, to the alleged deception

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[11] However, as we explain in Part B *infra*, damage actions are wholly outside the MDA's preemption provision because that provision differs materially from the one at issue in *Cipollone* and the FDA has reasonably construed the MDA to preempt only positive enactments of state and local governments.

of petitioner and her doctor (21a n.8), which obviously has nothing to do with the PMA approval process. Furthermore, as the court of appeals noted (19a), the preemption of the fraud claims is in direct conflict with the Fifth Circuit's decision in *Hurley v. Lederle Laboratories*, 863 F.2d 1173, 1180 (1988), which held that a fraud cause of action was not preempted by FDA's approval of a vaccine's labeling.[12]

Given the incompatibility of the court of appeals' decision with other lower court decisions as well as with *Cipollone*, this Court should grant review.

B. Review Should Be Granted Because, Contrary to the Holding Below, The MDA, as Authoritatively Construed by the FDA, Does Not Preempt Any Common Law Damage Claims.

The First Circuit's decision also warrants this Court's consideration because, in finding that all of petitioner's claims were preempted, the court necessarily held that Congress intended to preempt common law damage claims. In doing so, the court of appeals rejected petitioner's contention that Congress intended to limit the preemptive scope of § 360k to the positive enactments of state and local governments. While the courts have expressed differing views on the preemptive scope of § 360k -- generally finding preemption of at least some types of damage claims -- the preemption of state-law damage claims ascribes to Congress an intent that cannot be squared with the statutory language, the legislative history, or the FDA's regulations.

In *Cipollone*, this Court held that, under the Smoking Act of 1969, a "requirement ... based on smoking and health ... imposed under state law" was a reference to a common law damage claim, as well as positive statutory and regulatory law. 112 S. Ct. at 2620-21. It did so on the basis of various statutory indicia, including legislative history and a change made from a prior version of the Act, all of which pointed in the direction of preemption of some damage claims. *Id.*

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[12] We note that this circuit conflict is not vitiated by the Fifth Circuit's ruling in *Stamps v. Collagen Corp.*, 984 F.2d 1416 (1993), which generally followed the decision below, because *Stamps* expressly did not reach the fraud claims. *Id.* at 1422 n.5.

Thus, while "a requirement ... *under state law*" may, in some circumstances, include common law claims, review of the specific provision at issue here -- 21 U.S.C. § 360k -- demonstrates that damage claims are not preempted under the MDA. Section 360k(a) does *not* refer generally to all "state law," language that was critical to the analysis in *Cipollone*; it says that "no State or political subdivision of a State may establish or continue in effect with respect to a device" certain requirements. In some situations, a "requirement" under § 360k(a) may encompass a judicial order (such as the enforcement or the interpretation of a state law or regulation concerning devices), *see* 21 C.F.R. § 808.1(b); however, it strains ordinary English usage well past the breaking point to say that a jury award to a tort plaintiff such as petitioner constitutes a "State or political subdivision of a State establish[ing] or continu[ing] in effect" a device requirement, especially when measured against the strong presumption against preemption that animates this Court's jurisprudence. *See Mortier*, 111 S. Ct. at 2482, 2485.

Read most naturally, § 360k(a) concerns state and local statutes, ordinances, and regulations that impose affirmative requirements on device manufacturers, such as those at issue in *New Jersey Guild, supra*. Not surprisingly, neither the legislative history, H.R. Rep. No. 94-853, 94th Cong., 2d Sess. 4, 45-46 (1976), nor the extensive regulatory history, concerning both the scope of FDA preemption in general and the Agency's regulatory decisions on whether specific state requirements are preempted, even suggest, let alone make explicit, that common law remedies are preempted. Rather, the legislative history and the FDA's regulatory comments are replete with references to the preemption provision's application to the actions of state and local legislative and regulatory bodies.[13]

Indeed, as we noted earlier (*supra* at 14-15), shortly after passage of the MDA, the FDA issued regulations making clear that tort-like remedies are not preempted. "State or local requirements

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[13] H.R. Rep. No. 94-853, 94th Cong., 2d Sess. 4, 45-46 (1976); 45 Fed. Reg. 67,321-67,324 (Oct. 10, 1980); 43 Fed. Reg. 18,662-18,664 (May 2, 1978); *see also Callan v. G.D. Searle & Co.*, 709 F. Supp. 662, 667 (D. Md. 1989)(relying on legislative history).

of general applicability" that "relate[] to other products in addition to devices ... or to unfair trade practices in which the requirements are not limited to devices" are not preempted. 21 C.F.R. § 808.1(d)(1). Thus, damage claims based on common law duties would not be preempted because they "generally pertain ... to persons who manufacture or distribute devices ... ," and other tortfeasors, "and [do] not [pertain] directly to devices." 43 Fed. Reg. 18,661, 18,663 (May 2, 1978).[14] "In order for a State provision to be a requirement with respect to a device within the meaning of section 521 of the act -- and thereby a candidate for preemption -- it must relate to the device itself." *Id.* This is precisely why the FDA, in an advisory opinion, rejected the preemption holding in *National Women's Health Network, Inc. v. A.H. Robins Co., Inc.*, 545 F. Supp. 1177, 1181 (D. Mass. 1982), where the plaintiff had sought a warning to all users of the Dalkon Shield intrauterine device *under Massachusetts tort law*. The FDA stated that "the act preempts only State and local requirements that directly and specifically relate to devices" (26a). Thus, "*[r]ules or requirements established by States to govern the legal remedies available under the State judicial system are not 'requirements with respect to a device' within the meaning of section 521(a) of the act*" (*id.*)(emphasis added).[15]

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[14] That is why, contrary to the decision below, the only state or local regulations preempted by PMA requirements for a specific device are state-based PMA procedures themselves. *See, e.g.*, 45 Fed. Reg. at 67,323 (states may require pre-market approval of a specific device, even after passage of MDA, until FDA requires such approval for that device).

[15] This advisory opinion (25a-26a) was issued by the FDA's Associate Commissioner for Regulatory Affairs pursuant to delegated authority, *see* 21 C.F.R. § 808.5, and represents at least as strong a barometer of FDA policy as did the regulatory commentary deferred to by this Court in *Hillsborough County, Fla. v. Automated Medical Laboratories, Inc.*, 471 U.S. 707, 714 (1985)(deferring to FDA's position narrowly construing preemption of state and local regulation of blood donation centers, despite comprehensive federal regulation). Moreover, the FDA advisory opinion was reiterated by the Chief of FDA's Regulations Staff in a February 1987 letter, which stated that 21 U.S.C. § 360k(a) "preempts only state and local requirements that are specifically related to medical devices. Therefore, *FDA believes that section 521 [§ 360k(a)] does not preempt general product liability requirements*" (27a)(emphasis added).

Moreover, the existence of 21 U.S.C. § 360k(*b*) -- a provision mentioned only in passing by Judge Tourrella (7a), and not at all by Judges Aldrich and Campbell -- further undermines the contention that § 360k(a) is applicable to common law claims. Subsection (b) allows States or their political subdivisions to apply to the FDA for exemptions, so that they can maintain requirements that are otherwise preempted. Subsection (b)'s language is parallel to that of subsection (a), *i.e.*, it permits exemption of any requirement that may be preempted under subsection (a), and thus allows applications only from "States or political subdivisions" to exempt "requirements" "applicable to a device for human use." 21 U.S.C. § 360k(b).

The legislative history of subsection (b) also makes clear that exemptions may be sought for anything preempted under subsection (a), and refers solely to the exemption of "regulation[s]" and other positive enactments issued pursuant to state law. H.R. Rep. No. 94-583, *supra* at 45. Therefore, the FDA's exemption regulations construing subsection (b) begin by stating that a "State or political subdivision may apply ... for an exemption from any requirement it has *enacted* ... ." 21 C.F.R. § 808.20(a)(emphasis added); *see also id.* § 808.20(c)(1)(requiring jurisdiction seeking exemption to submit "any statute, rule, regulation or ordinance" for which exemption is sought). Thus, subsection (b) does *not* apply to the establishment of common law duties or jury awards. To suggest that subsection (a), however, does apply to damage awards makes no sense and would impose upon § 360k an awkward and illogical asymmetry that is flatly contradicted by the statute and the FDA's regulations.

We recognize that most courts, *see Lindquist v. Tambrands, Inc.*, 721 F. Supp. 1058, 1062 n.2 (D. Minn. 1989)(collecting cases), have held that subsection (a) can preempt some common law claims, but almost all of them -- like the court of appeals here -- have simply assumed that conclusion, and *none* of the courts finding preemption has even considered the effect of subsection (b). The one court to have considered subsection (b) in a damage action held that "[t]he plain language of § 360k indicates that Congress intended to preempt state or local legislation and administrative regulations governing devices, not state tort law." *Callan v. G.D. Searle & Co.*, 709 F. Supp. 662, 667 (D. Md. 1989)(alternative holding). The court explained that, "if the term

'requirement' were interpreted so as to include tort law, the exemption provision [of 21 U.S.C. § 360k(b)] would be rendered absurd; is the State supposed to petition the Secretary of Health and Human Services after every verdict in favor of an IUD tort plaintiff?"[16]

In petitioner's view, the MDA plainly does not contain the "clear and manifest" Congressional purpose necessary to preempt any common law tort liability. *See Mortier*, 111 S. Ct. at 2482, 2485; *Cipollone*, 112 S. Ct. at 2626 & n.1 (Blackmun, J., concurring in part, concurring in the judgment in part, and dissenting in part). In any event, the First Circuit's decision that 21 U.S.C. § 360k(a) expressly ousts state law-based jury awards is sufficiently problematic to warrant review, especially given its evident incompatibility with the views of the FDA.[17]

C. Review Should Be Granted Because of the Manifest Importance of the Court of Appeals' Ruling.

As we noted at the outset, the former Chief Counsel of the FDA views the decision below as probably the most important medical-device case in history. This is not surprising because, even if viewed as applying only to Class III devices currently subject to pre-market approval, the court of appeals' decision would preempt all claims against the manufacturers of millions of potentially deadly devices, such as heart valves, 21 C.F.R. § 870.3925, breast implants, *id.* § 878.3540, intraocular lenses, *id.* § 886.3600, various implantable devices for the treatment of epilepsy and other neurological disorders, *id.* §§ 882.5820-.5840,

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[16] *Accord Kociemba v. G.D. Searle & Co.*, 680 F. Supp. 1293, 1298 (D. Minn. 1989)(dicta); *cf. New Jersey Guild*, 384 A.2d at 813-14 (existence of § 360k(b) is strong evidence of narrow preemptive scope of § 360k(a)). In addition, at least two district courts have held in unreported decisions that § 360k(a) does *not* preempt any common law claims. *Discussed in Berger v. Personal Products, Inc.*, 797 P.2d 1148, 1151 & n.16 (Wash. 1990).

[17] Given the tension between the FDA's pronouncements and the rulings of some courts, including the court below, this Court may want to invite the Solicitor General to express the Agency's views, as it did in *Kievlan v. Dahlberg Electronics, Inc.*, 78 Cal. App. 3d 951 (1978), *appeal dismissed*. 440 U.S. 951 (1979), an early MDA preemption case. *See also* 18a (FDA's interpretation of the statute must give way to court of appeals' understanding of MDA).

and hundreds of other devices intended to improve or sustain human life. The decision below displaces virtually all state-law remedies against the manufacturers of such devices, regardless of the extent of the patient's injuries or the manufacturing or design defects, even if FDA approval was procured through the manufacturer's fraud.

In petitioner's view, the court of appeals paid too little attention to the statute and regulations and instead employed a cost/benefit analysis, deciding that the MDA favored the marketing of new devices at the expense of "a few individuals [who] may be denied full protection ... " (15a). This perspective is best illustrated by the court's charge that petitioner is among the "idiosyncratic individuals" (19a) for whom a remedy must give way to the exigencies of the marketplace. However, poor device design and manufacturing practices, and fraud in the procurement of FDA Class III approval, has been blamed for the deaths of hundreds of heart valve recipients, who, because the device went through the PMA process, presumably would be without a remedy under the First Circuit's approach.[18] Similarly, there would be no remedy for patients injected with an opthalmic gel used to facilitate implantation of intraocular lenses that proved to be unduly dangerous, despite having received FDA approval.[19] Indeed, in this case, although there is no specific evidence of widespread illness, Zyderm's true toll is unknown, given respondent's alleged underreporting of adverse incidents (A00479), which, among other things, led to a Congressional investigation (A00523-A00525).[20]

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[18] *See generally* Staff Report of the Oversight and Investigating Subcommittee of the Committee on Energy and Commerce of the U.S. House of Representatives, *The Bjork-Shiley Heart Valve: "Earn As You Learn"* (GPO Feb. 26, 1990).

[19] *See* Oversight and Investigating Subcommittee of the Committee on Energy and Commerce of the U.S. House of Representatives, *Less Than the Sum of its Parts -- Reforms Needed in the Organization, Management, and Resources of the FDA's Center for Devices and Radiological Health* 31-33 (GPO May 12, 1993).

[20] *See generally id.* (describing serious problems with various devices, including Zyderm (at 23-24)); *see also supra* note 3.

At bottom, the court of appeals' economic analysis may or may not be correct, but it has nothing to do with whether Congress expressly intended to preempt state-law damage claims for Class III devices and has no basis in this Court's Supremacy Clause jurisprudence, which has been loathe to preempt state damage claims, where, as here, "Congress [has] fail[ed] to provide any federal remedy for persons injured by" respondent. *Silkwood*, 464 U.S. at 251. As the foregoing discussion indicates, "Congress would [not], without comment, remove all means of judicial recourse for those injured by [the] illegal conduct" of device manufacturers, as the FDA itself has recognized in its regulations and other authoritative pronouncements. *Id.*; *accord English v. General Electric Co.*, 496 U.S. 72, 87-90 (1990); *Callan*, 709 F. Supp. at 667.

CONCLUSION

The petition for a writ of certiorari should be granted.

Respectfully submitted,

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June 13, 1993

In the United States Court of Appeals
for the First Circuit

No. 92-1278

JANE KING
Plaintiff, Appellant

v.

COLLAGEN CORPORATION,
Defendant, Appellee.

APPEAL FROM THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS
[Hon. A. David Mazzone, U.S. District Judge]

Before
Torruella, Circuit Judge,
Aldrich and Campbell, Senior Circuit Judges.

Clinard J. Hanby, with whom Susan A. Allinger, John O' Quinn, O'Quinn, Kerensky & McAninch, Michael M. Essmyer, Michael M. Essmyer & Associates, Frank Lynch and LeComte, Emanuelson, Tick & Doyle, were on brief for appellant.

Bob Gibbins and Jeffrey R. White, were on brief for the Association of Trial Lawyers of America, amicus curaie.

Joseph J. Leghorn, with whom Peter T. Wechsler, Warner & Stackpole, Joe W. Redden, Jr., W. Curtis Webb, and Beck, Redden & Secrest, were on brief for appellee.

Bruce N. Kuhlik, Lars Noah, Covington and Burling, Edwin H. Allen, and Retta M. Riordan, were on brief for Health Industry Manufacturers Association, amicus curaie.

January 15, 1993

TORRUELLA, Circuit Judge. Jane King appeals from a grant of summary judgment entered in favor of Collagen Corporation ("Collagen") by the United States District Court for the District of Massachusetts. The district court determined that plaintiff's claims were preempted by the Medical Device Amendments of 1976 ("MDA"), 21 U.S.C. § 360c et seq. Because the district court correctly construed the preemption provision of the MDA, we affirm.

FACTS

Defendant Collagen manufactures and distributes Zyderm, a cosmetic medical device used to correct wrinkles and other skin deformities. Zyderm treatment consists of injecting processed cow tissue directly under the skin. Zyderm then supports the skin from underneath, smoothing out deformities on the surface of the skin. The course of treatment may run for several weeks and requires up to six applications. Researchers at Stanford University developed Zyderm in the early 1970's and Collagen placed it on the market in the early 1980's.

As a medical device, Zyderm falls within the scope of the MDA and thus must be approved and regulated by the Food and Drug Administration ("FDA"). As a Class III medical device under the MDA scheme, it is subject to the most extensive pre-marketing approval requirements imposed by the MDA and to similarly extensive regulation post-approval. The premarket approval process is designed to provide a "reasonable assurance of ...safety and effectiveness" for medical devices which are too dangerous or unknown to permit less regulation. 21 U.S.C. § 360(1)(c). Post-approval regulation is designed to keep the FDA apprised of ongoing safety findings or any other information about the device as it becomes available. Id. §§ 360e(e) & 360i(a).

Pursuant to the pre-marketing approval process, the FDA requires applicants to submit proposed labeling, extensive safety testing data and descriptions of manufacturing methods and materials. Id. § 360e(c)(1). Upon reviewing the materials in a comprehensive manner, the FDA may approve the device for sale or return the application to the applicant for further information or testing. Id. § 360e(d)(1). When the FDA returns an application to the applicant, the FDA must apprise the applicant of how to

correct all deficiencies. Id. § 360e(d)(2). Once the device is approved, the FDA retains the power to withdraw approval of the product permanently or suspend its approval temporarily if it determines that the device has become unsafe or its labeling inadequate. Id. § 360e(e)(1)(3). To assist the FDA in making these determinations, manufacturers must maintain records and make reports to the FDA on information pertinent to the device. Id. § 360i(a). Zyderm passed through the Class III approval process prior to marketing, and underwent revisions to the original approval afterwards.

Appellant Jane King sought Zyderm treatment in 1987. Following the normal procedure, Ms. King's physician administered a test dose of Zyderm before proceeding with the full treatment. Shortly after receiving this test dose, Ms. King suffered muscle and joint pains as well as other symptoms. Her doctor subsequently diagnosed her as having dermatomyositis/polymyositis ("DM/PM"), an autoimmune disease in which the immune system attacks skin and muscle tissue as if it were a foreign substance.

When Ms. King received Zyderm, Zyderm's FDA-approved labeling contraindicated use by those with a personal history of autoimmune disease. Since that time, however, the FDA has gradually allowed Collagen to change the labeling as it related to autoimmune disease. By 1991, Zyderm was no longer contraindicated for persons with a history of autoimmune disease. The FDA required a warning in 1991, however, that some recipients have suffered from unwanted autoimmune reactions, but that no causal connection between Zyderm and these reactions has been shown.

Ms. King subsequently filed a first amended complaint detailing seven claims against Collagen.[1] First, she claimed that

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[1] Ms. King filed suit against Collagen in 1990 alleging that the test dose of Zyderm caused her to develop DM/PM. Count one of her suit alleged that Collagen negligently tested, manufactured and sold Zyderm. Count two alleged that Collagen breached implied warranties of merchantability. Count three alleged fraud and deceit in the sale of Zyderm.

Ms. King subsequently filed the amended complaint. Appellee contends that Ms. King informed appellee that she would withdraw this amended complaint.

Collagen was strictly liable for her injuries because Zyderm was unsafe for its intended purpose and unreasonably dangerous to users. Second, she alleged that Zyderm was not safe and fit for the purpose intended and therefore sold in breach of the warranty of merchantability. Third, Ms. King alleged that negligence in the design, manufacture, marketing and sale of Zyderm, including negligence in not revealing dangerous propensities of the product, led to her injury. Fourth, she maintained that Collagen misbranded and/or mislabeled Zyderm. Fifth, she asserted that Collagen made misrepresentations of material fact to Ms. King in selling Zyderm to her. Sixth, she alleged that Collagen failed to warn her of any defective condition. Finally, Ms. King alleged that Collagen fraudulently obtained FDA approval.

Collagen moved for summary judgment shortly after Ms. King filed her amended complaint, arguing that FDA regulation of Zyderm under the MDA preempted all of the causes of action alleged in the complaint. The district court granted this motion, relying on a similar case from the Southern District of Texas. This case, Stamps v. Collagen Corp., No. H-90-2242, 1991 U.S. Dist. LEXIS 20666 (S.D. Tex. 1991), held that Plaintiff's various products liability claims arising out of Zyderm treatment were preempted by FDA regulation under the MDA.

LEGAL ANALYSIS

I.

Article VI of the Constitution dictates that federal law "shall be the supreme Law of the Land; and the judges in every State shall be bound thereby, any Thing in the Constitution or Laws of any State notwithstanding." U.S. Const. art. VI, cl. 2. State laws that conflict with federal laws and regulations, therefore, are preempted. E.g., Malone v. White Motor Corp., 435 U.S. 497

As such, appellee never opposed its entry. The district court entered the amended complaint, noting that no opposition was filed. The district court, however, proceeded to grant summary judgment on the basis of Ms. King's original complaint. Because the amended complaint contains essentially similar claims as the original complaint, with few additions, we will address the claims in the amended complaint.

(1978). In determining whether such a conflict exists, it is well settled that the intent of Congress governs. That is, preemption does not occur unless Congress so intended. Rice v. Santa Fe Elevator Corp., 435 U.S. 497, 504 (1978).

Congress may express its intent to preempt state law explicitly in the language of the statute. Jones v. Rath Packing Co., 430 U.S. 519, 525 (1977). Congress may express its intent implicitly by passing an extensive statutory scheme that extensively covers the field of regulation. Fidelity Federal Sav. & Loan Ass'n v. de la Cuesta, 458 U.S. 141, 153 (1982). Implied preemption also occurs when a conflict between state and federal law makes compliance with both impossible, or when state law would frustrate the purpose and objectives of the federal law. Id. (citing Florida Lime & Avocado Growers, Inc. v. Paul, 373 U.S. 132, 142-43 (1963); Hines v. Davidowitz, 312 U.S. 52, 67 (1941)).

We are aided in our determination of preemption in this case by the Supreme Court's recent treatment of the subject in Cipollone v. Liggett Group, Inc., 112 S. Ct. 2608 (1992). In Cipollone, a victim of lung cancer sued several cigarette manufacturers for breach of warranties contained in cigarette advertisements, for failure to warn of health hazards related to smoking, for fraudulently misrepresenting those hazards to the public, and for conspiracy to deprive the public of important health information. Id. at 2613. The cigarette manufacturers contended that petitioner's claims were preempted by the federal law requiring a health warning to appear on all cigarette advertisements and containers.[2] Id. at 2614.

In analyzing preemption, the Court relied only on the specific language of the provision regarding preemption. The Court reasoned that "Congress' enactment of a provision defining the preemptive reach of a statute implies that matters beyond that reach are not preempted." Id. at 2618. The opinion thus analyzed

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[2] That law stated that "[n]o requirement or prohibition based on smoking or health shall be imposed under State law with respect to the advertising or promotion of any cigarettes the packages of which are labeled in conformity with the Provisions of this Act." Federal Cigarette Labeling and Advertising Act of 1965, § 5, as amended by Public Health Cigarette Smoking Act of 1969, § 2, 15 U.S.C. § 1334.

each of petitioner's claims in light of the express language of the preemption provision in the cigarette warning statute.

The plurality held that the provision preempted failure to warn claims as to advertising practices, but not as to testing or research practices. Id. at 2621-22. The plurality reasoned that the Act only preempted state law claims arising out of cigarette advertising and promotion, and that appellant's claims arising out of testing and research did not relate to advertisement and promotion. The provision preempted petitioner's fraudulent misrepresentation claim that cigarette advertising neutralized the effect of the warning in a similar fashion. Id. at 2623-24. The provision, however, did not preempt fraud claims arising out of communication other than advertising, such as information required to be disclosed to an administrative agency, or out of fraudulent statements made in the advertising but unrelated to the health warning. Id.

The plurality further held that the provision did not preempt express warranty claims, because those claims arose due to the conduct of the manufacturers who made the warranties rather than from state law. Id. at 2622. Finally, the plurality held that the provision did not preempt the conspiracy to deprive the public of material facts claims, because they did not arise out of state law pertaining to smoking and health, but rather arose out of a "duty not to conspire to commit fraud." Id. at 2624.

The analysis of the plurality in Cipollone guides our analysis in this case. We begin by noting that the express preemption provision in the MDA, 21 U.S.C. § 360k, forecloses inquiry into implied preemption, because the fact that Congress included it in the MDA implies that matters beyond its reach are not preempted. Further, we note that the Cipollone plurality carefully construed the preemption provision to extend no further than its language warranted. In doing so, the plurality sought to pay proper respect to federal-state relations. This concern arises out of "the assumption that the historic police powers of the states [are] not to be superseded by . . . Federal Act unless that [is] the clear and manifest purpose of Congress." Cipollone, 112 S. Ct. at 2617 (citing Rice, 331 U.S. at 230). We too will carefully construe the preemption provision of the MDA to give due regard to questions of federal-state relations.

II.

Bearing these principles in mind, we turn to the language of the statute in question. The MDA states that

> (a) Except as provided in subsection (b) of this section, no State or political subdivision of a State may establish or continue in effect with respect to a device intended for human use any requirement--
>
> (1) which is different from, or in addition to, any requirement applicable under this chapter to the device, and
>
> (2) which relates to the safety or effectiveness of the device or to any other matter included in a requirement applicable to the device under this chapter.

21 U.S.C. § 360k. Under subsection (b) of § 360k, a state may petition the FDA in certain circumstances to allow state requirements to continue in force. Because no such petition affects this case, we are concerned only with the preemptive effect of subsection (a). Under subsection (a), we must determine whether appellant's products liability claims give rise to state law requirements in addition to or different from those mandated by the FDA.

We turn first to the FDA's own understanding of subsection (a) for guidance. See Chevron U.S.A., Inc. v. Natural Resources Defense Council, Inc., 467 U.S. 837 (1984) (agency's interpretation of its own statute is controlling so long as not contrary to Congress' intent). FDA regulations provide that preemption does not apply when the FDA has issued no regulations or other requirements specific to the particular device. 21 C.F.R. § 808.1(d). In this case, it is clear that the requirements on Zyderm related to labeling, design, manufacturing and other aspects of the device pursuant to the MDA scheme.

If the FDA has issued requirements for a device, subsection (a) prohibits states from imposing any requirements which differ from or add to the FDA requirements, or which relate to the safety or effectiveness of the device. A "State . . . requirement" in subsection (a) may emanate from any requirement established by

a state including statutes, regulations, court decisions or ordinances. 21 C.F.R. § 808.1(b); see also San Diego Building Trades Council v. Garmon, 359 U.S. 236, 247 (1959) ("[State] regulation can be as effectively exerted through an award of damages as through some form of preventive relief. The obligation to pay compensation can be, indeed is designed to be, a potent method of governing-conduct and controlling policy.").

The language of subsection (a) and the definition of state requirement promulgated under it demonstrate a field of preemption which is broad, but limited. Any state requirement which, in effect, establishes a new substantive requirement for the device in a regulated area such as labeling, is preempted. 21 C.F.R. § 808.1(d)(6)(ii). As the Seventh Circuit noted, however, subsection (a) of the MDA does not preempt such claims as negligent implantation or removal of devices, or claims arising out of contaminated devices. Slater v. Optical Radiation Corp., 951 F.2d 1330, 1334 (7th Cir. 1992), cert. denied, 1992 U.S. LEXIS 6436 (Oct. 13, 1992).

Armed with this understanding of subsection (a), we will analyze petitioner's claims individually to determine the effect of the MDA preemption provision on each.

A. Strict Liability

Appellant contends that Zyderm is unsafe for its intended purpose and unreasonably dangerous to users, and that Collagen therefore is liable for any injuries Zyderm may cause. Indeed, class III devices such as Zyderm are those that present a "potential unreasonable risk of illness or injury" such that extensive regulation is required to ensure reasonably safe use. 21 U.S.C. § 360c(a)(1)(C). The FDA must evaluate these devices with regard to those for whose use the device is intended. Id. § 360c(a)(2)(A). The entire MDA scheme for such Class III devices as Zyderm, therefore, is aimed at determining and regulating the intended purpose of the device, and at ensuring a reasonable level of safety for its users.

It is clear that appellant's strict liability claim would impose requirements related to the safety and effectiveness of Zyderm. If successful, the claim would require Collagen to redesign Zyderm, remove it from the market, or be subject to strict liability. The

MDA does not permit this. Appellant's claim would force us to determine that Zyderm is unsafe and dangerous, in opposition to the contrary determination made by the FDA under the MDA. Subsection (a) protects manufacturers of medical devices approved by the FDA under the MDA from such state law intrusion.

B. Breach Of Warranty

Appellant claims that Collagen breached express and implied warranties of merchantability and fitness for a particular purpose. Appellant's express warranty claims arise out of the labeling and packaging of Zyderm, all of which are regulated by the FDA. In labeling and packaging, Collagen could not say any less than what the FDA required, and appellee could openly add extra warnings or safety information, but not warranties, without FDA approval. Appellant's express warranty claims therefore are preempted because any such warranties only could arise out of the FDA-approved labeling and packaging. Allowing appellant's express warranty claims effectively would impose additional or different requirements on Zyderm's labeling and packaging.

We note that the Court's holding in Cipollone would seem to require the opposite result in this case. However, the warnings at issue in Cipollone were different than those here. In Cipollone, the statute required cigarette manufacturers to include a brief health warning in their advertisements; this warning did not affect cigarette advertisements in any other way. The manufacturers were free to make any claims they wished, including express warranties. Here, however, the MDA has imposed much more extensive regulation upon class III device manufacturers. The FDA retains rigid control over the entirety of the labeling and packaging of class III products, largely displacing the ability of manufacturers to make additional claims. This high level of control contrasts with the low level of control in Cipollone, and ensures that manufacturers will not be held liable for packaging and labeling imposed by the FDA.

Appellant also alleges that Collagen breached an implied warranty of merchantability, and that this breach caused her injuries. As an implied warranty is a requirement upon a product that arises exclusively from the operation of state contract law, this

claim is preempted expressly by the MDA. Otherwise, it would impose a requirement additional to those imposed under the MDA.

C. Negligence

Appellant's third claim alleges negligence in the design, manufacture, marketing and sale of Zyderm. This claim also is preempted by the MDA. If the MDA does nothing else, it regulates the design, manufacture, sale and marketing of class III medical devices in an extensive way. The MDA does this through the packaging and labeling requirements which directly affect the marketing and sale of the product. The same requirements also affect the design and manufacture of the product in that these processes must be approved by the FDA and described in the product's packaging and labeling.

As the design, manufacture, marketing and sale of Zyderm is the subject of FDA regulation, the negligence claim is preempted. Otherwise, a finding of negligence would force Collagen to alter these aspects of Zyderm in response to the finding of liability, or be subject to liability. Either result impermissibly would impose an additional or different state requirement upon the design, manufacture, marketing and sale of Zyderm.

D. Product Misbranding, Misrepresentation & Failure to Warn

Appellant contends that Zyderm was misbranded or mislabeled. Misbranding generally occurs when labeling is "false or misleading" in any particular. 31 U.S.C. § 352(a). Under the MDA, the FDA must reject proposed labeling when the labeling is "false or misleading in any particular." Id. § 360e(d)(2)(D). As there is no indication in the record that the Zyderm administered to Ms. King was anything but what the FDA-approved labeling said it would be, notwithstanding appellant's bald statements, we find this claim preempted.

Appellant's fifth and sixth claims of misrepresentation and failure to warn are preempted for similar reasons. A finding that Collagen misrepresented Zyderm to appellant would impose a requirement on Collagen to change its packaging or labeling in order to correct the misrepresentation. The failure to warn claims

similarly challenge the adequacy of Zyderm's FDA-regulated packaging and labeling. The MDA forecloses these claims because Collagen cannot be forced to change Zyderm's packaging and labeling by virtue of these state law damage claims.

E. Fraud

Appellant's final cause of action alleges that Collagen fraudulently obtained FDA approval at the premarketing stage of the MDA process, and asks for treble damages due to the fraud. This cause of action is more unclear than her other causes of action. Collagen insists that the claim originally was based upon Mass. Gen. L. ch. 231, § 85J, an antifraud statute, while appellant urges that it was based on a more general duty not to deceive.

Section 85J provides that "[w]hoever, by deceit or fraud, sells personal property shall be liable in tort to a purchaser in treble the amount of damages sustained by him." The language of this statute corresponds to Ms. King's fraud claim in providing for treble damages. Because Ms. King has not specified any applicable statute, or other reason why she is entitled to treble damages under a general duty not to deceive, we must conclude that the fraud claim originally arose under § 85J. The district court made the same finding in its memorandum and order in this case.

To state a claim for fraud under § 85J, the plaintiff must be in privity with the seller. Kourouvacilis v. General Motors Corp., 410 Mass. 706, 575 N.E.2d 734, 735 (1991). In this case, no privity existed between appellant and Collagen, as Collagen only sold its product directly to appellant's physician. Thus, as a matter of Massachusetts law, appellant's fraud claim must fail.

We further note that the fraud claim is, at bottom, a failure to warn claim. It seeks to show that Collagen had a duty to provide different information in Zyderm's packaging and labeling than that which was approved by the FDA. As such, the claim is preempted expressly by the MDA.

CONCLUSION

Because we have determined that the MDA expressly preempts Ms. King's state law tort claims, the judgment of the district court is affirmed.

"Concurrence follows"

ALDRICH, Senior Circuit Judge, with whom CAMPBELL, Senior Circuit Judge, joins, concurring. While we agree with our brother Torruella's result, and a good deal that he says, we approach this case somewhat differently. First, a matter of housekeeping. On December 13, 1991, a year past the scheduled date for completion of the pleadings, plaintiff filed a motion to allow an amended complaint, accompanied by the complaint. On December 17 she wrote defendant that she would withdraw her motion. Defendant, accordingly, did not oppose. On December 27 defendant moved for summary judgment. In opposing defendant's motion for judgment plaintiff made no mention of the proposed new complaint, but, in fact, she did not withdraw her motion, and the court later allowed it. However, the court's ultimate order granting summary judgment did not mention the amendment.

At first blush we might agree with defendant's objection that there were substantive additions in the amended complaint, particularly with relation to fraud. Apart from fraud, the rest of the amended complaint contains six claims as against, originally, two -- negligence and breach of implied warranty. There was definitely a purported enlargement -- a state tort of strict liability, and a claim of express warranty. While the negligence alleged is limited to designing and producing a dangerous product, and not that the sample sold plaintiff was in some way a departure and individually defective, plaintiff adds mislabeling and misrepresentation, and, finally, failure to warn.

Taking defendant's now alleged seven sins, we group them as follows. Strict liability (negligent design), implied warranty, negligence, mislabeling, and failure to warn are really all of a piece -- failure to warn. On the record it is clear that had there been a warning that the product might cause the disease that plaintiff allegedly suffered she would have no claim under any of these headings. On this basis there is thus no real enlargement by the amended complaint. Express warranty might be enlargement,

but there is no basis for claiming it.[3] Finally, fraud and misrepresentation are not as newly put as they look. Defendant would have it that the original allegation related only to representations made to the plaintiff. Plaintiff states that she intended her language to include misrepresentations to the agency. Two of her exhibits seeking to raise an issue on the motion for summary judgment bear this out. The amendment should stand, as mere clarification. However, we read fraud more broadly than does our brother, and shall return to it later.

All agree that there is one basic issue: federal preemption. Preemption may apply against state judicial as well as legislative action,[4] Cipollone v. Liggett Group, Inc., 112 S. Ct. 2608 (1992), and may take two forms, express and implied, with a heavy burden upon the party asserting it. Jones v. Rath Packing Co., 430 U.S. 519, 525 (1977). This is especially so when the subject is the state interest in health and safety. Hillsborough County v. Automated Medical Labs, Inc., 471 U.S. 707, 715, 718-19 (1985). The question is Congressional intent. Wood v. General Motors Corp., 865 F.2d 395, 401 (1st Cir. 1988), cert. denied, 494 U.S. 1065 (1990). Here, concededly, the statute's purpose is health protection, but the parties disagree as to its scope. Plaintiff says it is directed to the individual user by keeping harmful products off the market and assuring proper warnings. Defendant says it is also to benefit the public at large by shielding regulated manufacturers against inconsistent state regulation, including lawsuits. If their legal risks may be too great, worthwhile medical devices may be left in the laboratory, to the public's loss.

Public health is a valid federal purpose, and Congress can reasonably weigh possible loss to the idiosyncratic few against

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[3] Express warranty might have created a problem for the defense of preemption, cf. Cipollone v. Liggett Group, Inc., 112 S. Ct. 2608, 2622-23 (1992).

[4] A matter that may have troubled the court in Wood v. General Motors, post. See, also, 21 C.F.R. 808.1(b).

benefits to the public generally. See, e.g., Mary Beth Neraas, The National Childhood Vaccine Injury Act of 1986: A Solution to the Vaccine Liability Crisis? 63 Wash. L. Rev. 149 (1988). The legislative history shows that this was precisely the Congressional intent. Concededly, the U.S. Code Congressional and Administrative News, 94th Congress, Second Session, Vol. 3, pp. 1070 et seq., Medical Device Amendments of 1976, shows the principal emphasis to be on the protection of the individual user. But it also shows the intent to "encourage. . . research and development" and "permit new and improved devices to be marketed without delay." Infra. Perfection is impossible and a few individuals may be denied full protection at the cost of benefitting the rest.

Contained within the Senate Report (94-33)[5] are the following.

> As medicine progresses, as research makes new breakthroughs, an increasing number of sophisticated, critically important medical devices are being developed and used in the United States. These devices hold the promise of improving the health and longevity of the American people. The Committee wants to encourage their research and development. [1071]
>
> S. 2368 recognizes the benefits that medical research and experimentation to develop devices offers to mankind. It recognizes, too, the need for regulation to assure that the public is protected and that health professionals can have more confidence in the performance of devices. [1075]
>
> The Committee recognizes the rapidly changing nature of the devices field and therefore feels that provisions must be made to amend standards on the basis of improved technology or new scientific evidence. Such amendments should

> be made in an expedited fashion so that appropriate changes can be rapidly implemented. The purpose of this authority is to permit new or improved devices to be marketed without delay so that the public may have such beneficial devices available to them as soon as possible. [1083]

Translating to a simple concept, and taking the difference of opinion between the parties to be whether the FDA requirements are merely minimum, or are the total maximum protection afforded the individual user, we believe this a clear demonstration of Congressional choice of the latter. We further find that the comprehensive statutory language conforms thereto.

21 U.S.C. § 360e(c)(1) provides,

> (1) any person may file with the Secretary an application for premarket approval for a class III device. Such an application for a device shall contain --
>
> > (A) full reports of all information, published or known to or which should reasonably be known to the applicant, concerning investigations which have been made to show whether or not such device is safe and effective;
> >
> > (B) a full statement of the components, ingredients, and properties and of the principle or principles of operation, of such device;
> >
> > (C) a full description of the methods used in, and the facilities and controls used for, the manufacture, processing, and, when relevant, packing and installation of, such device;

(D) an identifying reference to any performance standard under section 360d of this title which would be applicable to any aspect of such device if it were a class II device, and either adequate information to show that such aspect of such device fully meets such performance standard or adequate information to justify any deviation from such standard;

(E) such samples of such device and of components thereof as the Secretary may reasonably require, except that where the submission of such samples is impracticable or unduly burdensome, the requirement of this subparagraph may be met by the submission of complete information concerning the location of one or more such devices readily available for examination and testing;

(F) specimens of the labeling proposed to be used for such device; and

(G) such other information relevant to the subject matter of the application as the Secretary, with the concurrence of the appropriate panel under section 360c of this title, may require.

Following these detailed requirements, and we note especially subsection (F), comes Section 360k(a).

> [N]o State or political subdivision of a State may establish or continue in effect with respect to a device intended for human use any requirement --
>
> > (1) which is different from, or in addition to, any requirement applicable under this chapter to the device, and
> >
> > (2) which relates to the safety of the device or to any other matter included in a requirement applicable to the device under this chapter.

Particularly in the light of the legislative history we read this as maximum protection and express preemption, leaving no need to seek implications. As all but one of plaintiff's sustainable claims are premised on a failure to warn, preemption here is unavoidable, given the subsection (F) requirement that labels be reviewed by the FDA.

It followed that most of plaintiff's arguments are beside the mark. A few, however, may deserve mention. Plaintiff claims that because of the regulation reported in 21 C.F.R. 814.39(d)(1), to the effect that a manufacturer "may," without prior approval, make certain changes that enhance safety, defendant had a duty to make such here. It is sufficient to say that to interpret "may" as "should" would unravel the entire garment. Second, citing Silkwood v. Kerr-McGee Corp., 464 U.S. 238, 251 (1984), plaintiff says that, if defendant is correct, she has no cause of action. Given an ambiguity, this objection is a factor in statutory construction, but, of itself, it cannot create an ambiguity, or there could never be preemption. Finally, plaintiff says that the FDA's preemption regulation, 21 CFR § 808.1(d) conflicts with our result. When a statute is clear the agency interpretation must give way. Hillsborough County, 471 U.S. at 714-15.

A more troublesome issue is the claim labeled fraud.

FRAUD

> . . . Defendant Collagen Corporation fraudulently obtained FDA approval of the Zyderm PMA, product and labeling, which was a producing or proximate cause of damage and injury to Plaintiff. Defendant further acted to suppress the facts, blame injuries or other causes that its product (sic) prevent disclosure of the true risks.[6] Plaintiff has a case in point.

In Hurley v. Lederle Laboratories Division of American Cyanamid Co., 863 F.2d 1173 (5th Cir. 1988), the court, though agreeing with the district court that the FDA regulation with respect to defendant's vaccine labeling was intended to be preemptive, remanded. At issue was the same tension between protecting idiosyncratic individuals and the public health. Balancing these, the Court concluded,

> [T]his issue should be presented to the jury in the form of special interrogatories, questioning whether and what information the manufacturer withheld from the FDA, if any, and whether possession of this information would have materially altered the content of the FDA's warning. This special procedure is justified by the federal interest in encouraging manufacturers to produce vaccines, in that those manufacturers need some assurance that if they follow certain prescribed procedures, such as including an FDA-approved warning, they are complying with the law.

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[6] As in the original complaint, plaintiff sought treble damages. Though not mentioned, presumably this demand involved Mass. G.L. c. 231, § 85J, that awards treble damages in certain cases of "deceit or fraud." We do not read it, however, as limiting the scope of plaintiff's claims.

Id. at 1180. With respect, one may wonder how "encouraging" manufacturers would view the ruling.[7] Rather, we side with the later case of Papas v. Upjohn Co., 926 F.2d 1019 (11th Cir. 1991), where the court said, at 1026 n.8,

> To the extent that Hurley purports to recognize an exception to federal preemption of common law tort labeling claims when the federal statute involved explicitly prohibits state regulation of labeling and the federal agency has received incomplete information from the manufacturer, we reject its holding at least as applied to FIFRA-regulated pesticides. Given the FIFRA regulatory scheme, it would be up to the EPA -- not a jury -- to determine first (1) whether the information provided was complete or inaccurate; (2) whether the omitted information is significant enough to mandate a change of label; and (3) how, if at all, the label should be corrected.

To prove fraud, plaintiff must show causality. Surely, where the FDA was authorized to render the expert decision on Collagen's use and labeling, it, and not some jury or judge, is best suited to determine the factual issues and what their effect would have been on its original conclusions. Further, if the court erred, and incorrectly posited the effect on the FDA's use and labeling decision this would impose a state requirement "which is different from, or in addition to, any requirement applicable . . . the device." 21 U.S.C. § 360k(a). In addition to running afoul of the general principle against implying personal cause of action, Royal Bus Group, Inc., v. Realist, Inc., 933 F.2d 1056 (1st Cir. 1991), plaintiff would be breaching the federal dyke in the absence of its keeper.

---

[7] Indeed, we are reminded of the observation that the British hanged a negligent admiral "pour encourager les autres." Voltaire, Candide, Ch. 23

Panas has been vacated and remanded for further consideration in light of Cipollone, 112 S. Ct. 2608, but we do not believe this to be a reversal on that point. Our position is consistent with Cipollone, that did not preempt fraud found to be outside the communication targeted by the regulation.[8] 112 S. Ct. at 2623-24.

[8] Plaintiff similarly presents a claim for misrepresentation, both to the public and to plaintiff's physician. As the record shows no statements to the public or physicians that go beyond those approved by the FDA, this claim collapses into that of fraud on the FDA.

UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

JANE KING,
Plaintiff

Civil Action
No. 90-12718-MA

vs.

THE COLLAGEN CORPORATION,
Defendant

MEMORANDUM AND ORDER

Mazzone, D.J. February 3, 1992

This is an action to recover damages for personal injuries allegedly incurred by the plaintiff as a result of receiving a dose of collagen implant manufactured by the defendant. She brings claims of negligent testing, manufacture and sale of the Collagen implant; breach of warranty of merchantability; and the sale of personal property by deceit or fraud, M.G.L. c. 231, § 85J. The matter is before me on the defendant's motion for summary judgment. The record is complete. The sole issue presented is whether the claims presented by the plaintiff are pre-empted by the Medical Device Amendment to the Food, Drug & Cosmetic Act, 21 U.S.C. §§ 360 c, et seq., and the regulations promulgated thereunder.

After careful review of the record and the relevant case law, I am persuaded by the clear, cogent analysis and careful reasoning presented by Chief Judge James DeAnda in Jennifer Stamps v. Collagen Corporation, Memorandum Opinion, Civil Action No. H-90-2242, U.S.D.C., S.D. Texas (October 11, 1991), (appeal pending).

I do not believe I can add anything to the discussion. That opinion addresses all of the issues presented here, including the plaintiff's allegations that the defendant's conduct was fraudulent. There are no factual issues in dispute. I conclude that the implants in this case are subject to the specific, detailed requirements of the Food, Drug and Cosmetic Act and, therefore, the plaintiff's claims are pre-empted. See also Moore v. Kimberly-Clark Corp., 867

F.2d 243 (5th Cir 1989) and Tarallo v. Searle Pharmaceutical, Inc., 704 F. Supp. 653 (D.S.C. 1988).

Accordingly, the defendant's motion for summary judgment is allowed.

SO ORDERED.

s/ A. David Mazzone
United States District Judge

UNITED STATES COURT OF APPEALS
FOR THE FIRST CIRCUIT

No. 92-1278

JANE KING
Plaintiff, Appellant

v.

THE COLLAGEN CORPORATION
Defendant, Appellee.

Before

Torruella, Circuit Judge
Aldrich and Campbell, Senior Circuit Judges

ORDER OF COURT

Entered: February 3, 1993

Plaintiff's petition for rehearing, that shows extraordinary disregard of our Internal Operating Procedures X, "Petitions...are not to be used for reargument of an issue previously presented," is denied.

By the Court

FRANCIS P. SCIGLIANO, CLERK.

By_____
Chief Deputy Clerk

[cc: Messrs. Lynch, Hanby, Essmyer, Leghorn, Wacheler, Redden, Webb and Ms. Allinger]

DEPARTMENT OF HEALTH & HUMAN SERVICES
Public Health Service
Food & Drug Administration
Rockville, MD 20857

MAR -8 1984

National Women's Health Network
c/o Robert E. Manchester, Esq.
Manchester & O'Neill, P.C.
Attorneys at Law
P.O. Box 1459
Burlington, Vermont 05402-1459

Re: Docket No. 83A-0140/AP

Dear Mr. Manchester:

This letter is in response to your letter of April 25, 1983, submitted on behalf of your client, the National Women's Health Network (the network). You requested an advisory opinion under 21 CFR 808.5, 10.85, 10.20, and 10.30(c)(1), declaring that section 521 of the Federal Food, Drug, and Cosmetic Act (the act)(21 U.S.C. 360k) does not preempt the application of State law injunctive remedies to intrauterine contraceptive devices (IUDs) produced, marketed, and inserted into women prior to the enactment of the Medical Device Amendments of 1976 (Pub. L. 94-295) and still being worn by women in the United States and other countries.

Section 521(a) of the act contains special provisions governing the regualtion of devices by States and localities. That section prescribes a general rule that after May 28, 1976, no State or political subdivision of a State may establish or continue in effect with respect to a medical device intended for human use any requirement having the force and effect of law (whether established by statute, ordinance, regulation, or court decision), which is different from, or in addition to, any requirement applicable to such device under any rpovision of the act and which relates to the safety or effectiveness of the device or to any other matter included in a requirement applicable to a device under the act. Under

section 521(a) of the act, the act preempts only State or local requirements that directly and specifically relate to devices. For a State provision to be a requirement with respect to a device within the meaning of Section 521 of the act, and thereby a candidate for preemption, it is necessary that the State provision relate to the device itself. There is no indication in the legislative history of section 521(a) that Congress intended that the section preempt State or local requirements respecting general enforcement, including available legal remedies, or State or local statutes that only incidentally apply to devices. Rules or requirements established by States to govern legal remedies available under the State judicial system are not "requirements with respect to a device" within the meaning of section 521(a) of the act.

FDA also advises that section 521(a) of the act preempts State or local requirements applicable to adevice only when FDA has established specific counterpart regulations or there are other specific requirements applicable to a particular device or class of devices under the act; it is necessary that an FDA requirement exist before a State requirement is preempted. There is no FDA counterpart (regulations or specific requirements applicable to IUDs) to the State provisions the network has invoked in National Women's Health Network, et. al. v. A.H. Robins Company, Inc., No. 81-0004-N (D. Mass. filed January 2, 1981). Thus, those State provisions are not preempted under section 521(a) of the act.

In conclusion, FDA believes that section 521(a) of the act does not preempt the application to IUDs of State law injuctive remedies. This advisory opinion does not address the merits of the application of such remedies in any action filed by the network in the State of Massachussets or any other State.

Sincerely yours,
s/
Joseph P. Hile
Associate Commissioner
for Regulatory Affairs

cc: [omitted]

DEPARTMENT OF HEALTH & HUMAN SERVICES
Public Health Service
Food & Drug Administration
Rockville, MD 20857

FEB 02 1987

Cindy Whaley, Esquire
Winston, Cashatt
Attorneys at Law
Seattle First Financial Building
Spokane, WA 99201

Dear Ms. Whaley:

Enclosed is the information that you requested in our phone conversation of January 27, 1987 regarding preemption and medical devices. As you can see from these FEDERAL REGISTER documents, it is the Food and Drug Administration's (FDA) position that section 521 of the Federal Food, Drug and Cosmetic Act (21 U.S.C. 360(k)) preempts only state and local requirements that are specifically related to medical devices. Therefore, FDA believes that section 521 does not preempt general product liability requirements.

If I can be of any further assistance to you, please let me know.

Sincerely yours,
s/
Joseph M. Sheehan
Chief, Regulations Staff

Enclosures

(2)

AUG 16 1993
OFFICE OF THE CLERK

No. 92-1979

IN THE
Supreme Court of the United States
OCTOBER TERM, 1993

JANE KING,
Petitioner,

v.

COLLAGEN CORPORATION,
Respondent.

On Petition for a Writ of Certiorari to the United States Court of Appeals for the First Circuit

---

BRIEF FOR THE RESPONDENT IN OPPOSITION

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August 1993

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QUESTION PRESENTED

Whether the Medical Device Amendments of 1976—which expressly preempt state requirements relating to safety or effectiveness that are different from or in addition to federal requirements—bar state tort claims against the manufacturer of a medical device whose design and labeling met the specific requirements imposed by the Food and Drug Administration as conditions of premarket approval.

CORPORATE AFFILIATES

Pursuant to Rule 29.1, the following is a list of all parent companies and subsidiaries (except wholly owned subsidiaries) of respondent Collagen Corporation: Target Therapeutics, Inc., CollOptics, Inc., Prograft Medical, Inc., and LipoMatrix, Inc.

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IN THE

Supreme Court of the United States

OCTOBER TERM, 1993

No. 92-1979

JANE KING,

Petitioner,

v.

COLLAGEN CORPORATION,

Respondent.

On Petition for a Writ of Certiorari to the United States Court of Appeals for the First Circuit

---

BRIEF FOR THE RESPONDENT IN OPPOSITION

STATEMENT OF THE CASE

Petitioner Jane King filed this state-law tort action against respondent Collagen Corporation ("Collagen") in Massachusetts superior court in 1990. Collagen removed the case to the United States District Court for the District of Massachusetts on the basis of diversity of citizenship. The district court granted summary judgment in favor of Collagen on the ground that petitioner's claims were expressly preempted under section 521 of the Federal Food, Drug, and Cosmetic Act ("FD&C Act"), 21 U.S.C. § 360k, as added by the Medical Device Amendments of 1976. Pet. App. 22a-23a. The court of appeals affirmed. *Id.* at 1a-22a.

Zyderm.® Collagen manufactures and distributes Zyderm Collagen Implant (injectable bovine collagen), a prescription medical device used to correct human skin deformities. On April 30, 1980, after years of research, development, and clinical testing, Collagen submitted an application for premarket approval to the United States Food and Drug Administration ("FDA"). More than one year later, after an exhaustive review of the evidence concerning Zyderm's safety and effectiveness, FDA approved the application. 46 Fed. Reg. 46394 (September 18, 1981) (concluding that Zyderm is "safe and effective for use as recommended in the submitted labeling").

Requirements imposed by FDA. Zyderm is regulated by FDA as a "class III" medical device, a category of devices subject to comprehensive FDA requirements governing all aspects of their design and labeling and requiring FDA approval prior to marketing. *See* 21 U.S.C. § 360e. The agency's requirements for class III devices are the most sweeping and stringent of all those imposed under the device classification scheme. *See* 21 U.S.C. § 360c. A class III device such as Zyderm can be marketed only pursuant to a license granted by FDA, which imposes specific requirements governing its manufacture and labeling. (Class I devices, such as bandages, and class II devices, such as tampons, are not subject to the same premarket approval process. Instead, manufacturers of those devices need comply only with general regulations and, in some cases, requirements applicable to specific aspects of the device.)

FDA's approval of Collagen's premarket approval application ("PMA") for Zyderm created a private license permitting the manufacture and sale of the device only in accordance with the design and labeling approved by FDA through the PMA process. Any deviation from the conditions for approval of a PMA would be a *per se* violation of the FD&C Act. 21 U.S.C. § 351(f)(1). "A device may not be manufactured, packaged, stored, labeled, distributed, or advertised in a manner that is inconsistent

with any conditions to approval specified in the PMA approval order for the device." 21 C.F.R. § 814.80. Thus, through premarket approval, FDA establishes detailed requirements regarding the design and labeling of a class III device in advance of sale.

Even after approval, manufacturers of such devices are subject to comprehensive recordkeeping and reporting obligations to ensure that they obtain and report to FDA the most up-to-date information bearing on the safety and effectiveness of a marketed medical device. 21 U.S.C. § 360i; 21 C.F.R. pt. 803. The agency has broad authority to withdraw approval of a class III device, and it often directs manufacturers to add or modify labeling for a device to take into account new information about side effects. For example, FDA originally approved labeling for Zyderm to contraindicate patients who had a personal or immediate family history of autoimmune disease; in 1983, FDA approved a labeling revision to contraindicate only those patients with a personal history of the disease; and in 1991 FDA approved deletion of the contraindication in favor of a warning that some patients had reported autoimmune reactions but that no causal connection had been shown. Pet. App. 3a.

Proceedings below. Petitioner sought treatment with Zyderm in 1987. After her doctor administered a skin sensitivity test, petitioner complained of muscle and joint pains allegedly arising from a condition later diagnosed as dermatomyositis/polymyositis (DM/PM). Pet. App. 3a. Thereupon, petitioner sued Collagen in Massachusetts state court, seeking damages for negligence in the testing, manufacture and sale of Zyderm and for breach of implied warranties of merchantability, and treble damages for sale of personal property by deceit or fraud in violation of Massachusetts law (Mass. Gen. L. ch. 231, § 85J). Pet. App. 22a.

Collagen removed the case to federal court and filed a motion for summary judgment on December 27, 1991,

arguing that petitioner's claims were preempted by federal law, specifically, section 521 of the FD&C Act, 21 U.S.C. § 360k. Section 521 preempts any state requirement relating to safety or effectiveness that is different from, or in addition to, a federal requirement applicable to the device in question. The district court (Mazzone, J.) granted Collagen's motion for summary judgment. Pet. App. 22a-23a.

The court of appeals affirmed, finding that all of petitioner's state-law claims were expressly preempted under section 521. Pet. App. 1a-21a. In his opinion for the court, Judge Torruella analyzed petitioner's claims pursuant to this Court's decision in *Cipollone v. Liggett Group, Inc.*, 112 S. Ct. 2608 (1992). Pet. App. 5a-6a. As required by *Cipollone*, he concluded that section 521 applies to state tort actions, because such actions impose "requirements" within the meaning of the law. *Id.* at 7a-8a.

Judge Torruella noted FDA's view, as expressed in the agency's regulations, that "[a]ny state requirement which, in effect, establishes a new substantive requirement for the device in a regulated area such as labeling, is preempted." Pet. App. 8a. He determined that FDA did in fact impose specific requirements for the labeling and design of Zyderm through the PMA process. *Id.* at 7a-8a.

Judge Torruella then analyzed each of petitioner's claims separately. He determined that petitioner's claims of strict liability, breach of warranty, negligence, misbranding, and failure to warn all were predicated upon the imposition of requirements different from or in addition to those imposed by FDA, and thus that they are expressly preempted by section 521. Pet. App. 8a-11a. He also rejected petitioner's claim of fraud because the Massachusetts statute on which that claim was based requires privity with the seller, and "no privity existed between [petitioner] and Collagen." *Id.* at 11a.

Senior Judges Aldrich and Campbell concurred in a separate opinion. Pet. App. 13a-21a.[1] The concurring judges noted that Congress enacted the preemption statute to encourage research and development in the medical device area, for the purpose of furthering the public health. *Id.* at 14a-15a. Analyzing the language of section 521, they found it to be a "clear demonstration of Congressional choice" in favor of the view that specific FDA requirements represent "the total maximum protection afforded the individual user," rather than "merely the minimum." *Id.* at 16a. They explained that insofar as petitioner's "sustainable claims are premised on a failure to warn, preemption here is unavoidable," *id.* at 18a, because such claims would effectively impose requirements beyond those established by FDA. As to petitioner's remaining claim of fraud, the concurring judges concluded that, to the extent it could be construed as an allegation that FDA itself had been defrauded, the claim amounted to a request that a court or jury determine, impose, and enforce new and different labeling requirements based upon the information Collagen allegedly had suppressed during the premarket approval process; the imposition of such new and different requirements under the guise of state tort law, the judges noted, is expressly barred by section 521. *Id.* at 20a.

REASONS FOR DENYING THE PETITION

The court of appeals' decision is correct and, notwithstanding petitioner's assertions to the contrary, does not conflict with the decisions of this Court or of any other appellate court. The petition therefore should be denied.

---

[1] The unusual lineup of judges and opinions—a one-judge opinion for the court, with two judges concurring—makes it difficult to discern what in fact constitutes the views of the court of appeals. The concurring judges agreed with "a good deal" of what is said in Judge Torruella's opinion, but they "approach[ed] this case somewhat differently." Pet. App. 13a. To the extent that the differences in approach might make a difference to the result of some future case, it will be up to the First Circuit to clarify what it considers binding in these opinions.

The application of section 521 of the FD&C Act to approved class III devices such as Zyderm represents a straightforward exercise in express preemption. There can be little doubt that section 521 preempts state tort law actions with respect to class III devices that are subject to premarket approval requirements—every court squarely to address the issue has so held.

Section 521 preempts state requirements that are different from federal requirements. The terms of FDA's premarket approval impose specific federal requirements for labeling and design. State tort actions alleging, in substance, inadequacy in the labeling or design of a device subject to premarket approval thus are preempted.

In arguing that some courts have held otherwise, petitioner relies upon inapposite cases where the medical devices at issue were not class III devices subject to premarket approval; in those cases, no relevant federal requirements triggering preemption had been imposed. But in cases involving class III devices, the courts consistently have read section 521 to preempt state tort claims of the sort made by petitioner here.

Three federal courts of appeals now have so held (all in cases involving petitioner's counsel). Last year, this Court denied certiorari after the Seventh Circuit ruled that section 521 protects manufacturers of class III devices from state tort claims that implicate requirements different from those imposed by FDA. *Slater v. Optical Radiation Corp.*, 961 F.2d 1330, 1333 (7th Cir. 1992), *cert. denied*, No. 92-303 (October 13, 1992). The Fifth Circuit now has joined the Seventh Circuit in *Slater* and the First Circuit here in so ruling. *Stamps v. Collagen Corp.*, 984 F.2d 1416 (5th Cir. 1993), *pet. for cert. pending*, No. 98-1989 (filed June 13, 1993). There is thus a growing unanimity of treatment of this issue in the courts of appeals. There is no reason or need for plenary review of the issue by this Court.

1. When it added section 521 to the FD&C Act as part of the Medical Device Amendments of 1976, Congress expressly preempted competing state requirements:

> [N]o State or political subdivision of a State may establish or continue in effect with respect to a device intended for human use any requirement—
>
> (1) which is different from, or in addition to, any requirement applicable under this Act to the device, and
>
> (2) which relates to the safety or effectiveness of the device or to any other matter included in a requirement applicable to the device under this Act.

21 U.S.C. § 360k(a). The crux of this case is that petitioner's tort claims would erect "requirements" beyond those specifically established by the FDA, and hence they are preempted.

Petitioner's argument (Pet. 20-24) that the term "requirement" does not encompass state tort claims cannot prevail in light of this Court's decision in *Cipollone v. Liggett Group, Inc.*, 112 S. Ct. 2608 (1992). There, six Members of the Court concluded that similar language in the Public Health Cigarette Smoking Act of 1969 applied to state tort claims. *Id.* at 2619-21 (Stevens, J.); *id.* at 2632-38 (Scalia, J.). Every lower federal court to have addressed the question since *Cipollone* has similarly concluded that preemption statutes applicable to state "requirements" cover common law claims as well as positive enactments. *See, e.g., Arkansas-Platte & Gulf v. Van Waters & Rogers,* 981 F.2d 1177, 1179 (10th Cir. 1993), *pet. for cert. pending,* No. 92-1784 (filed May 10, 1993) (preemption under the Federal Insecticide, Fungicide, and Rodenticide Act); *Papas v. Upjohn Co.*, 985 F.2d 516 (11th Cir. 1993) (same).

Petitioner argues principally (Pet. 12-13) that there are no federal "requirements" applicable to Zyderm that could give rise to preemption under section 521. This

argument, which rests on a fundamental misapprehension of the federal regulatory scheme for class III devices, was extensively considered and rejected below. Pet. App. 2a-3a, 8a-10a, 16a-18a.

Class III devices are subject to the most extensive level of federal regulation, and to the most specific federal requirements governing all aspects of their design and labeling. The manufacturer must submit full information on these and other aspects of the device to FDA before marketing, and commercial distribution can proceed only upon FDA approval of the PMA application.[2] *See* Pet. App. 16a-17a. The approval represents a license to market the product in accordance with the precise conditions specified by FDA to ensure the safety and effectiveness of the device. *See* 21 U.S.C. § 360e. These conditions—which specify how the particular device in question must be manufactured and labeled—are the federal "requirements" that cannot be supplemented by the states under section 521.

To be sure, these requirements are made applicable through the terms of the premarket approval rather than through regulations. But section 521 is not limited to federal requirements imposed by regulations. As FDA itself has explained, state requirements are preempted when FDA "has established specific counterpart regulations *or* there are *other specific requirements* applicable to a *particular device* under the act," 21 C.F.R. § 808.1 (d) (emphasis added), and "[f]or a device classified in class III . . . , the counterpart FDA requirement [is] the requirement that the product have premarket approval," 43 Fed. Reg. 18661, 18664 (May 2, 1978). *See also*

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[2] For example, the manufacturer must submit to FDA "full reports of all information" regarding whether or not the device is safe and effective; a "full statement of the components, ingredients, and properties" of the device; a "full description of the methods used" to manufacture the device; samples of the device, if requested by FDA; the labeling proposed to be used for the device; and any other relevant information required to be submitted by FDA. 21 U.S.C. § 360e(c)(1).

45 Fed. Reg. 67321, 67323 (October 10, 1980) (when FDA establishes a premarket approval requirement for a class III device, state law is preempted).

Both opinions below followed the claim-by-claim preemption analysis established by *Cipollone*. Given the existence of federal labeling and design requirements, it is beyond dispute that petitioner's numerous failure-to-warn and negligent or inadequate design claims are preempted. Pet. App. 8a-11a, 13a-14a, 18a.[3] Petitioner's single remaining claim, relating to alleged fraud, was ill-defined and, procedurally, was not properly presented below.[4] In any event, the court of appeals rejected that claim on state-law grounds (lack of privity). Pet. App. 11a. The concurring judges further explained that petitioner's claim of fraud on patients or physicians was devoid of record support, *id.* at 21a n.8, and that any claim of fraud on FDA itself was simply a disguised attempt to impose state requirements different from those imposed by FDA. *Id.* at 20a.[5] None of these various alternative holdings warrants further review.

---

[3] Petitioner's variously stated claims that Zyderm was not accompanied by adequate warnings, and was not properly manufactured or designed, fly in the face of FDA's determination that the product is safe and effective when labeled and manufactured in accordance with the requirements of the PMA approval. Petitioner never alleged that Collagen manufactured or marketed Zyderm in violation of any of those federal requirements.

[4] The district court ruling was based on petitioner's original complaint. The court of appeals did not resolve Collagen's procedural objection that petitioner's amended complaint was not properly on appeal. The court nonetheless addressed the amended complaint, reasoning that it contained only a "few additions" to the original complaint. Pet. App. 3a-4a n.1; *see also id.* at 13a-14a. To the extent that those additions expand petitioner's fraud (and other) claims, Collagen reiterates its objection that the amendment cannot stand because petitioner had represented in the district court that she would withdraw the amended complaint. Collagen also objects to petitioner's belated effort (Pet. 5-6 n.3, 25 n.20) to introduce extra-record evidence to support her fraud claim.

[5] In substance, petitioner's claim was that, in the absence of the alleged fraud, FDA would have imposed different labeling re-

2. The lower courts have consistently held that section 521 expressly preempts state tort claims challenging aspects of a device's design or labeling that are subject to federal requirements. Two other courts of appeals have so held in the only other appellate cases to address the issue involving class III devices. *See Stamps v. Collagen Corp.*, 984 F.2d 1416 (5th Cir. 1993), *pet. for cert. pending*, No. 92-1989 (filed June 13, 1993) (approved class III device); *Slater v. Optical Radiation Corp.*, 961 F.2d 1330 (7th Cir.), *cert. denied*, 113 S. Ct. 327 (1992) (class III device subject to investigational device requirements). Similarly, numerous courts have held that section 521 expressly preempts failure-to-warn claims for class II devices, such as tampons, for which warning requirements have been specified by FDA. *See, e.g., Moore v. Kimberly-Clark Corp.*, 867 F.2d 243, 246 (5th Cir. 1989); *Berger v. Personal Products, Inc.*, 797 P.2d 1148, 1150-51 n.9 (Wash. 1990), *cert. denied*, 111 S. Ct. 1584 (1991) (collecting cases).

There is no conflict. The tampon cases cited by petitioner (Pet. 17) find preemption of warning claims; they do not extend preemption to design claims, but only because there are no specific FDA design requirements applicable to those class II devices. Class III devices subject to premarket approval, such as Zyderm, are subject to FDA design requirements, and thus preemption under section 521 reaches design claims against such devices. *See Stamps v. Collagen Corp., supra*, 984 F.2d at 1421 (Fifth Circuit relied on its own tampon decision in *Moore*

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quirements for the device, and Collagen should be held liable under state law for failing to adhere to those different requirements. But it is the very fact that petitioner is seeking the imposition of different requirements that renders her claim preempted under section 521.

To the extent that petitioner would recast the claim as one resting on alleged violations of federal reporting requirements, it must be rejected because there is no private cause of action under the FD&C Act. Pet. App. 20a; *see also, e.g., Florida ex rel. Broward County v. Eli Lilly & Co.*, 329 F. Supp. 364 (S.D. Fla. 1971).

to find broad preemption of tort claims with respect to class III devices). The hearing aid cases upon which petitioner relies (Pet. 15-16) likewise involved neither class III devices nor state-law claims at odds with FDA requirements.[6] And *Hurley v. Lederle Laboratories*, 863 F.2d 1173 (5th Cir. 1988), which petitioner cites as a conflicting decision with respect to her fraud claim (Pet. 20), did not involve section 521 at all; it involved a vaccine regulated under a different statute, the Biologics Act, 42 U.S.C. § 262, which does not contain a preemption provision.

Petitioner never brought the other purportedly conflicting case she cites (Pet. 13), *Larsen v. Pacesetter Systems, Inc.*, 837 P.2d 1273 (Haw. 1992), to the attention of the court of appeals even though *Larsen* was decided shortly after argument and nearly four months before she filed her petition for rehearing below. In any event, *Larsen* is, at bottom, wholly different; the device there was not subject to any requirements imposed by FDA as part of the class III premarket approval process.[7] As the *Larsen* court itself explained, the notice process at issue in that case " 'is not equivalent to an approval by the FDA of the device's safety and effectiveness.' " 837 P.2d at 1282 (citation omitted). The Fifth Circuit in *Stamps*, in holding that tort claims are preempted with respect

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[6] *See Smith v. Pingree*, 651 F.2d 1021 (5th Cir. Unit B 1981); *New Jersey Guild of Hearing Aid Dispensers v. Long*, 384 A.2d 795 (N.J. 1978). These pre-*Cipollone* cases principally dealt with state requirements governing the fitting and dispensing of hearing aids, as to which there are no federal requirements. *Smith* also upheld a state "disclaimer" provision that used language substantially identical to a counterpart federal requirement and differed only as to where the disclaimer would be provided. *See* 651 F.2d at 1025.

[7] Although a Class III device, the pacemaker at issue in *Larsen* was marketed pursuant to a grandfather provision that allowed pre-1976 devices and any "substantially equivalent" devices to remain on the market, at least until such time as FDA imposes a PMA requirement for that category of devices. 21 U.S.C. §§ 360(k), 360e(b).

to *approved* class III devices, correctly distinguished *Larsen* on this basis. *See* 984 F.2d at 1423 & n.6. *See also* 21 C.F.R. § 801.97 (permission to market in accordance with notification procedure "does not in any way denote official approval of the device"). Finally, the *Larsen* court also recognized that common law claims could be preempted in the event that specific FDA requirements applied to the device in question, and it cited the Seventh Circuit's decision in *Slater* approvingly. *See* 837 P.2d at 1281-82.

3. The decision below also is consistent with FDA regulations interpreting section 521. In the first place, FDA agrees that section 521 preempts state requirements established through court decisions: section 521 reaches "any requirement with respect to a medical device intended for human use having the force and effect of law (whether established by statute, ordinance, regulation, or *court decision*), which is different from, or in addition to, any [federal] requirement applicable to such device . . . ." 21 C.F.R. § 808.1(b) (emphasis added). Moreover, as noted above (pages 8-9), FDA interprets the statutory reference to federal requirements to include those imposed through PMAs, as occurred in this case. Both the court below (Pet. App. 7a) and the court in *Stamps* (984 F.2d at 1421 nn. 1 & 2) concluded that preemption was consistent with FDA's regulations.

In the face of section 521 of the FD&C Act and section 808.1(b) of the regulations, petitioner relies (Pet. 20) on two statements by FDA officials, an advisory opinion and an informal letter, to urge that FDA does not interpret section 521 to preempt state tort actions.[8]

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[8] Petitioner also cites (Pet. 21-22) passages in section 808.1(d) to dispute the clear import of the phrase "court decision" in section 808.1(b), but subsection (d) merely confirms the unremarkable fact that generally applicable requirements such as the Uniform Commercial Code are not preempted. This says nothing, however, about whether those state laws can be applied in a way that imposes substantive requirements on a device that differ from the require-

Neither of these pre-*Cipollone* statements would be entitled to any weight even if they purported to restrict section 521 in the manner suggested by petitioner: the plain statutory language controls, and thus the term "requirements" must be accorded its obvious meaning.

In any event, the two statements by FDA officials are irrelevant to the issue presented here. The advisory opinion was addressed only to the question whether state injunctive remedies may be made available with respect to intrauterine devices "produced, marketed and inserted into women *prior* to the enactment of [section 521]." Pet. App. 25a (emphasis added). The opinion thus has nothing to do with the issue in this case. In particular, the advisory opinion does not purport to clarify the phrase "court decision" as used in 21 C.F.R. § 808.1(b); indeed, the regulation is never even cited in the opinion.

The letter on which petitioner relies (Pet. App. 27a) simply reiterates that general common law standards are not preempted unless directly applied to a device that is subject to FDA requirements. Here, of course, petitioner seeks such a direct application. In any event, such informal correspondence is entitled to no weight to the extent that it would conflict with the clear terms of FDA's regulation. 21 C.F.R. § 10.85(k).[9]

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ments imposed by FDA. As to that fact situation, the regulation makes clear that preemption would apply (§ 808.1(d)(6)(ii)). Moreover, the laundry list in subsection (d) of general requirements that are not preempted does *not* include tort claims, thus confirming that FDA intended those to be treated as among the requirements imposed through "court decision" that are preempted under subsection (b).

[9] Finally, petitioner reads section 521(b) of the Act, which allows states to petition for an exemption from the preemptive effect of section 521(a), as a limitation on the scope of preemption (Pet. 23). Petitioner argues that subsection (b) does not apply to common law claims, and thus that subsection (a) must not either. But this argument is pure bootstrapping. There is nothing in subsection (b) which limits it in the manner petitioner contends. To the contrary, as petitioner concedes, the language of

4. Petitioner incorrectly asserts that the decision below leaves "*all* patients who are injured by Class III medical devices . . . without a remedy." Pet. 11 (emphasis in original). Under section 521, as correctly construed below and in such cases as *Stamps* and *Slater*, plaintiffs are entitled to recover for injuries caused by the violation of federal requirements, such as the conditions established by an applicable PMA or FDA regulation, if such a violation constitutes negligence or is otherwise actionable under state law.[10] And of course section 521 has no application to devices that are not subject to federal requirements or to state claims that do not implicate such requirements.[11]

Beyond those considerations, it should be remembered that, in the eye of the law, a plaintiff is injured not by a device but by a defendant's violation of a legal duty. The central purpose of section 521 is to limit a manufacturer's relevant legal duties in order to encourage the development and marketing of socially beneficial medical devices. *See* Pet. App. 14a-16a. By proscribing the imposition of additional state duties, such as strict liability standards and other state tort doctrines invoked by petitioner, Congress has rejected petitioner's facile equation of physical harm with legal injury. As the concurring

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subsections (a) and (b) "is parallel" (Pet. 23), and as the court of appeals correctly held pursuant to *Cipollone*, subsection (a) applies to common law claims; subsection (b) thus applies to them as well.

[10] In many jurisdictions, violations of FDA requirements may constitute negligence *per se*. *See Stanton v. Astra Pharmaceutical Products, Inc.*, 718 F.2d 553, 565 (3d Cir. 1983) (failure to report adverse drug experiences); *Orthopedic Equipment Co. v. Eutsler*, 276 F.2d 455, 460-61 (4th Cir. 1960) (device misbranding). *Cf. Merrell Dow Pharmaceuticals Inc. v. Thompson*, 478 U.S. 804 (1986) (state tort claims founded on alleged violations of FDA requirements did not present a federal question).

[11] *See Slater, supra*, 961 F.2d at 1334 (medical malpractice claims alleging improper implantation or removal of intraocular lenses would not be preempted).

judges below correctly recognized, "[p]ublic health is a valid federal purpose, and Congress can reasonably weigh possible loss to the idiosyncratic few against benefits to the public generally." *Id.* at 14a-15a.

Accordingly, section 521 means that plaintiffs cannot ask judges and juries to second-guess FDA's safety and utility determinations for medical devices whose labeling and design it has reviewed and approved. That is the decision *expressly* made by Congress, for the purpose of furthering the development of innovative medical technology (Pet. App. 15a-16a); and thus petitioner's invocation of various presumptions guiding *implied* preemption analysis (Pet. 11) is beside the point. *See Cipollone, supra,* 112 S. Ct. at 2620-22 (Stevens, J.).

CONCLUSION

For the foregoing reasons, the petition should be denied.

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No. 92-1979

In The Supreme Court Of The United States
October Term, 1992

Jane King,

Petitioner,

v.

The Collagen Corporation,

Respondent.

On Petition for Writ of Certiorari to the
United States Court of Appeals for the First Circuit

Brief of Alabama, Alaska, American Samoa, Arizona, Arkansas, Connecticut, Delaware, Florida, Hawaii, Idaho, Indiana, Massachusetts, Minnesota, Missouri, Nevada, New Mexico, North Carolina, North Dakota, Northern Mariana Islands, Ohio, Pennsylvania, South Carolina, Tennessee, Texas, Utah, Vermont, Wisconsin, and Wyoming as Amici Curiae in Support of Petitioners

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Pursuant to Rule 37 of the Rules of this Court, Alabama, Alaska, American Samoa, Arizona, Arkansas, Connecticut, Delaware, Florida, Hawaii, Idaho, Indiana, Massachusetts, Minnesota, Missouri, Nevada, New Mexico, North Carolina, North Dakota, Northern Mariana Islands, Ohio, Pennsylvania, South Carolina, Tennessee, Texas, Utah, Vermont, Wisconsin, and Wyoming as amici curiae, respectfully submit this brief in support of the petitions for writ of certiorari submitted by Jane King in No. 92-1979 and Jennifer Stamps in No. 92-1989.[1]

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[1]Amici have submitted, under separate cover, identical briefs on both petitions, and refer in both briefs to the decisions of both the First and Fifth Circuit Courts of Appeals and to both the King and Stamps petitions.

Statement of Interest

The Courts of Appeals for the First and Fifth Circuits have decided that the States may not provide their citizens with tort law remedies for injuries caused by dangerous medical devices.

These decisions nullify the States' historic reliance upon tort law as the principal protection for their citizens from unsafe conduct and conditions. State tort law both compensates injured individuals, paying their medical and other expenses, and provides a powerful incentive to those who engage in potentially dangerous activities to minimize the risks of those activities. Through long processes of court decision and legislative action, the States have developed and refined their tort systems to balance the needs and rights of victims against the needs and rights of manufacturers of potentially dangerous products, such as the product that caused the injuries in these cases.

Where, as here, the States have exercised their basic powers to protect the health and welfare of their citizens, the federal courts must presume that there is no preemption of state action unless preemption is the "clear and manifest" intent of Congress. *Rice v. Sante Fe Elevator Corp.*, 331 U.S. 218, 230 (1947).

The States submit this brief in order to assist this Court in reviewing the petitions, and to urge this Court, in light of this presumption against preemption and the specific circumstances of this case, to restore to the States the ability to provide tort remedies to their citizens who have been injured by dangerous medical devices.

Summary of Argument

The Courts of Appeals have decided that the safety measures employed by private manufacturers of medical devices are, when approved by the FDA, and in some cases, even when they are not approved by FDA, federal requirements that preempt state law. Their decisions go far beyond this Court's decisions in this area, which have only found preemption of state safety-related law where the federal government itself has enacted a safety standard.

The decisions of the Courts of Appeals deprive persons injured by the most dangerous class of devices of their state tort law remedies for those injuries. The impact of this decision will be profound. Not only will persons injured by dangerous devices have no legal remedy for their injuries, but the amount of safety that users of all medical devices can expect will be severely diminished. The FDA's premarket approval process is inadequate to ensure device safety, both because it is an imperfect process based upon incomplete information, particularly about long term and less common safety hazards, and because the removal of possible state tort law liability creates incentives for manufacturers to be less than candid with the FDA about known safety hazards.

The decisions of the Courts of Appeals are based upon the mistaken belief that Congress, as a matter of policy, intended premarket approval to be the maximum protection provided to the public. The plain language of the statute itself undermines this misconception by providing for more stringent regulation by the states.

In reaching their decision, the Courts of Appeals ignored this Court's admonitions to interpret express preemption provisions of statutes primarily in light of the language of the statute itself. The plain language of the statute indicates that only state laws specifically relating to a particular medical device are preempted, and that state laws of general applicability, such as the common law of torts, are not.

This plain language interpretation is consistent with the interpretation of the statute adopted by the FDA when it promulgated its preemption regulations and with the interpretation of the only state supreme court to have considered the issue. The interpretations of the Courts of Appeals conflict with both the FDA's and the state supreme court's interpretations.

Finally, the Courts of Appeals decided that all of the petitioners' state law causes of action are preempted, including their breach of warranty and fraud claims. However, the statute at issue here is very similar to the statute at issue in *Cipollone v. Liggett Group, Inc.*, 505 U.S. ___, 112 S.Ct. 2608, 2618 (1992), which this Court held did not preempt causes of action based upon breach of warranty or fraud.

In sum, the Courts of Appeals have adopted a novel interpretation of a federal preemption statute. Their interpretation is contrary to the plain language of the statute, conflicts with both FDA and state court interpretations of the statute, and deviates from one of this Court's recent interpretations of a similar statute. Considering the dramatic impact that their interpretation will have upon the rights of persons injured by medical devices and the safety of the medical device using public, this Court should review this case and restore to the States their ability to provide their citizens with tort remedies for injuries caused by dangerous medical devices.

Argument

I. This Court should determine that federal approval of a manufacturer's medical device specifications does not preempt state tort law causes of action.

The Courts of Appeals have interpreted the Food, Drug, and Cosmetic Act as stripping away essentially all legal remedies for persons who are injured by class III medical devices, the most dangerous class of medical devices.[2] In place of those remedies, they have installed the Food and Drug Administration's ("FDA") premarket approval procedures as the sole source of public protection from these devices.

This interpretation of the medical device provisions of the Food, Drug and Cosmetic Act, which have not yet been considered by this Court, greatly impacts the health and well being of medical device consumers. It will not only prevent the petitioners here from obtaining redress for their injuries, but will prevent all persons who are injured by dangerous medical devices from being compensated for their injuries. Moreover, the Courts of Appeals' reliance upon premarket approval procedures to protect the public health is fundamentally misplaced, as those procedures alone are inadequate to ensure that class III medical devices are safe.

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[2]21 U.S.C. §360c(a)(1) establishes 3 classifications for medical devices: Class I, Class II, and Class III. Briefly, class I devices are devices for which the general provisions of the Act regarding misbranding, adulteration, good manufacturing practice and other matters are sufficient to provide reasonable assurance of safety and efficacy. Examples of class I devices include ice bags, tongue depressors, examination gloves, and crutches.

Class II devices are devices for which the general controls applicable to class I devices are insufficient to provide a reasonable assurance of safety and effectiveness, and for which there is enough information about the device to establish a special performance standard to provide that assurance. Examples of class II devices include: clinical electronic thermometers, intravascular catheters, and piston syringes.

Class III are devices which present too great a risk to be class I devices and for which insufficient information exists to establish a class II performance standard. Examples of class III devices include: replacement heart valves, intaocular lenses (for implantation into the eye), and contraceptive intrauterine devices (IUDs).

The impact of the Court of Appeals' decisions on the lives of persons who use medical devices is tremendous. This Court should consider and definitively determine the scope of preemption in the medical device area.

a. Federal approval of a manufacturer's medical device specifications is not a federal requirement that triggers preemption of state law.

This Court has not considered whether the kind of federal activity at issue here gives rise to preemption. The Courts of Appeals, without much analysis, held that FDA approval of a manufacturer's premarket application is a federal "requirement" which triggers preemption of state law. In fact, the role of the FDA in this area is substantially different from the federal role in other cases where this Court has found federal safety related activity to preempt state law. For example, in both *Cipollone* and *CSX Transportation, Inc. v. Easterwood*, 113 S.Ct. 1732 (1993), this Court's most recent pronouncements concerning federal health and safety requirements and state tort law, this Court found preemption where the federal government promulgated a safety standard with which compliance was mandatory. In *Cipollone*, Congress required specific warning statements to be included in cigarette advertising. In *CSX Transportation*, the Federal Railroad Administration set specific speed limits that were to be observed by railroad operators. In both cases, preemption was triggered by a specific standard promulgated by the federal government.

By contrast, the FDA's role with respect to an application for premarket approval is to merely determine, as a matter of fact, whether the application meets the statutory criteria for approval. If the application meets the criteria, then it must be approved. 21 U.S.C. § 360e(d). The specifications for the design, manufacture, and labeling of the device are set forth by the manufacturer in the application and they are solely the manufacturer's responsibility. 21 U.S.C. § 360e(c).

A manufacturer has broad discretion in how it structures its device specifications to meet the criteria for approval. If a device presents a particular safety hazard, a manufacturer, depending upon the nature of the hazard, may choose from a variety of options in minimizing the hazard. The manufacturer may redesign the device to eliminate the hazard, include a warning in the labeling of the device so that users may avoid the hazard, limit the indications for use of the device so it is not used in a manner that gives rise to the hazard, or take some combination of those actions. As long as the option chosen by the manufacturer supports a finding by the FDA that there is a "reasonable assurance that the device is safe under the conditions of use prescribed, recommended, or suggested in the proposed labeling" of the device, then the FDA must approve the manufacturer's application. 21 U.S.C. § 360e(d)(1)(A).

Once a manufacturer has obtained FDA approval, it is free to make substantial safety related modifications to the device without first submitting those modifications to the FDA for review. 21 C.F.R. § 814.39(d) permits the following changes to be made without prior approval of the FDA:

> i. Labeling changes that add or strengthen a contraindication, warning, precaution, or information about an adverse reaction.
>
> ii. Labeling changes that add or strengthen an instruction that is intended to enhance the safe use of the device.
>
> iii. Labeling changes that delete misleading, false, or unsupported indications.
>
> iv. Changes in quality controls or manufacturing process that add a new specification or test method, or otherwise provide additional assurance of purity, identity, strength, or reliability of the device.

By virtue of the nature of the premarket approval process and these regulations concerning post-approval modifications, device manufacturers have great latitude within which they can establish and modify their own substantive safety

specifications. By contrast, the cigarette manufacturers subject to federal warning requirements and the railroad operators subject to federal railway speed limits have no such discretion. For them, the federal government has established a substantive standard, from which they may not vary.

The device manufacturer's safety-related undertakings do not resemble federal safety standards so much as they resemble the undertakings of a warrantor who determines what characteristics a product will have and promises that the product will live up to those characteristics. In *Cipollone*, this Court held that an express warranty, because it was an undertaking of the manufacturer, was not a government requirement. *Cipollone*. at 2622. The same rationale should apply in this case. Because of the freedom accorded to manufacturers to pick and choose the safety measures they will include in their applications for premarket approval, those measures should not be treated as federal safety requirements that preempt state law.

b. The federal medical device approval process does not adequately protect the public health and should not serve as the public's sole protection from dangerous medical devices.

The devices which must be submitted for premarket approval, class III devices, must be so submitted because they present a potentially unreasonable risk of illness or injury and because their workings and effects on the human body are not well understood. 21 U.S.C. § 360c(a)(1)(C). Class III devices have not been generally used in medical practice, and there is no wide body of experience from which judgments of safety can be made. By definition, there is not enough information concerning these devices for the FDA to be able to promulgate a class II performance standard that would give a reasonable assurance of safety. 21 U.S.C. § 360c(a)(1)(C)(i)(II).[3] As result, the

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[3]It is useful to contrast the devices at issue here to the federal railroad speed limits at issue in *CSX Transportation*, and the federal health warnings at issue in *Cipollone*. With over one hundred years of experience with railroad transportation, it may fairly be said that railroad speed limits may be

FDA must act on an application for approval of a class III device without complete information about the safety of the device. In particular, it is most often without information about long term and less common side effects.

Typically, the FDA relies upon clinical studies, in animals and humans, to attempt to judge the safety of a proposed device. *See* 21 C.F.R. § 814.20 (required contents of application, with extensive discussion of requirements for clinical studies). Unfortunately, no clinical study can reliably identify all of the possible side effects, particularly the long range side effects, of a new device. Such studies are generally conducted only for a relatively short term and with a relatively small number of subjects. While they are useful in determining the gross effects of a device on the human body, they are not as reliable in detecting less common effects or effects which only manifest themselves over the long term. The FDA itself recognizes the inherent difficulties in relying upon clinical studies to determine the safety of devices, and as a result, almost always requires post-approval monitoring of problems that arise in connection with the actual use of devices in the marketplace. Because of the limitations on the information available for the kinds of devices that must go through the premarket approval process, it is not surprising that once a device is approved and marketed widely, significant safety hazards may be discovered.

The case at bar graphically illustrates the problems that can arise when a device is approved without complete information concerning the safety hazards it presents. Zyderm was approved for use by the FDA in 1981. However, it was not

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determined with a reasonable degree of confidence that the limits will ensure safety. Similarly, federal cigarette warnings were not promulgated until after years of scientific and public debate about the effects of smoking on health. By contrast when the FDA receives an application for approval of a brand new medical device, the hazards of the device are not entirely known, and the appropriate measures to minimize those hazards are also not well understood. In that environment, it is difficult to be confident that the approval process will ensure a desired level of safety. This Court should hesitate before ascribing to the premarket approval procedure the power to prevent future injuries to such an extent that it is no longer necessary to provide for a system of compensation for those injuries which do occur.

until several years later that a link between Zyderm and the disorder at issue here, dermatomyositis or polymyositis ("DM/PM"), was suspected. The linkage between DM/PM and Zyderm was primarily established by post-approval epidemiological evidence, which by its very nature can only be examined after a device has been widely used. In fact, the first published, peer reviewed study concerning this link did not appear until June of 1993, 12 years after Zyderm was initially approved by the FDA.[4] Because the information connecting DM/PM and Zyderm was unavailable to the FDA at the time of Zyderm's approval, the approval process provided no protection at all for the victims of this disorder.

Even if the FDA were able to know about all of the possible hazards presented by a device at the time the device is presented for approval, the premarket approval process has other shortcomings that render it inadequate as the sole source of public protection against dangerous devices.

The FDA cannot, as part of the premarket approval process, determine that a manufacturer will not negligently or intentionally alter the design, manufacture or labeling of a device in some way that might create a safety hazard. The FDA cannot ensure that a manufacturer will not negligently or intentionally make false or misleading statements about a device in advertising. Nothing in the premarket approval process provides any assurance that a manufacturer will conduct itself without negligence or other tortious conduct after its device has been approved. Indeed, given these facts and the freedom granted to manufacturers to make safety related changes to their devices after they have been approved, users of medical devices can never really be assured that the device they are using is the same as the device that was reviewed by the FDA.

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[4]Cukier, Beauchamp, Spindler, Spindler, Lorenzo, and Trentham, *Association between Bovine Collagen Dermal Implants and a Dermatomytosis or a Polymyositis-like Syndrome*, 118 Annals of Internal Medicine, June 15, 1993, at 921.

Because of the inherent difficulties in attempting to determine all of the risks posed by a particular device and the problems associated with monitoring manufacturer conduct after the device has been approved, FDA approval of the device provides only a minimum assurance of safety.[5] The Courts of Appeals have elevated this minimum assurance to the maximum assurance of safety that the public can have. This Court should intervene to preserve the measures that the States have taken to provide their citizens with additional protection.

c. State tort law is the only source of compensation for persons injured by dangerous medical devices and provides incentives for manufacturers to ensure safety both during the federal approval process and afterward.

The incentives provided by the state tort system make the premarket approval process work. The potential of tort liability for a serious safety defect provides an incentive for manufacturers to test their products thoroughly and to provide complete data to the FDA. It similarly motivates them to engage in rigorous post-marketing surveillance so that they will be alerted to any undiscovered safety hazards in as timely a manner as possible. These incentives are important, because without them, the regulatory scheme creates perverse incentives to suppress information about safety hazards.

In the environment created by the Courts of Appeals, a manufacturer of a Class III device need only look to the FDA for permission to market its device. As long as the FDA has approved the device and that approval is not withdrawn, the manufacturer may profitably market the device. That source of profit is jeopardized by any negative safety information that

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[5]This is not to say that FDA approval is useless. It serves as a vitally important screening point to eliminate the thousands of blatantly fraudulent, inadequately tested and quack devices that would flood the marketplace were FDA approval not a prerequisite for marketing all but the most innocuous (class I) or well understood (class II) devices. The point of this discussion is that as the sole source of public protection from class III devices, FDA approval is inadequate.

might cause the FDA to disapprove an application for premarket approval or to withdraw a previously granted application. While certainly most reputable manufacturers would still act upon negative safety information, there would be no sanction for manufacturers who either negligently or intentionally fail to do so. In such cases, the FDA's premarket review process would become a bureaucratic shell game with little real protective value.

In addition, as discussed above, there are situations in which a manufacturer can make significant safety related changes to an approved device or its labeling without seeking additional prior approval from the FDA. While the regulation permitting these changes is intended to permit manufacturers to immediately act upon safety problems that slip past premarket review or that are discovered after approval is given, they provide no protection for the public if manufacturers make these changes, either negligently or intentionally, in ways that cause additional injuries to consumers of devices. Only state tort laws impose duties with respect to these product changes.

Finally, and most importantly, the tort law system is the only mechanism by which persons injured by devices can be compensated for their injuries. Even where the federal government has taken over exclusive responsibility for ensuring safety in a particular industry, as is the case in the civilian nuclear power industry, this Court has been reluctant to deprive individual citizens of tort remedies for injuries resulting from that industry's activity. *Silkwood v. Kerr-McGee Corp.*, 464 U.S. 238, 251 (1984).

The Courts of Appeals have determined that manufacturers of Class III devices should be free of state tort liability. In so doing the Courts of Appeals have created a regulatory climate in which persons injured by dangerous medical devices have no legal remedy for their injuries and in which the sole protection for users of such devices is an imperfect FDA review process, which is itself undermined by the perverse incentives created by the elimination of tort

liability. In so doing, the Courts of Appeals have strayed beyond the reach of *Cipollone* and *CSX Transportation*. They have extended federal preemption of state safety law to areas where the federal government has not enacted its own safety standards, but has merely approved the safety standards of private manufacturers. Because this case raises both important safety issues and an unsettled extension of federal preemption law, this Court should grant the petitioner's request for review.

II. This Court should review the decisions below because they are inconsistent with this Court's Supremacy Clause jurisprudence and create judicial and administrative agency conflicts that only this Court can resolve.

a. The Courts of Appeals based their decisions on presumptions which conflict with the plain language of the express preemption provision here, in contravention of this Court's admonitions that express preemption provisions be interpreted by their own terms.

The touchstone for determining Congressional intent to preempt must be the language of the statute claimed to have preemptive effect, particularly when that statute contains an express preemption provision. *CSX Transportation, Inc.*, at 1737, *Cipollone*, at 2618.

However, instead of following to their logical and natural conclusion the basic principles of statutory construction employed by this Court, the Courts of Appeals, particularly the First Circuit, constructed their own views of congressional intent upon which they based their own erroneous interpretations of the statute.

The First Circuit, relying upon legislative history which had nothing to do with the preemption provision at issue, determined that the Congressional purpose was to establish FDA requirements as the maximum protection to be afforded the individual user. *King v. Collagen Corp.*, 983 F.2d 1130, 1138 (1st Cir. 1993). The court then concluded that the statutory language conformed to its view of congressional intent. *Id.*

The First Circuit's approach not only ignores this Court's established principles of statutory interpretation, the policy prescription upon which it is based is at odds with the language of the statute.

The savings clause in 21 U.S.C. § 360k(b) provides that the FDA may exempt state requirements from preemption if the state requirement "is more stringent than a requirement under this Act...." It is highly unlikely that Congress intended subsection (a) of 21 U.S.C. § 360k to establish the FDA's requirements for devices as the maximum level of public protection when in subsection (b) of the same provision it authorized states to enact and maintain more stringent requirements for devices. Clearly, as both Stamps and King argued to the Courts of Appeals, FDA requirements are minimum requirements which can be augmented by state requirements. The interpretations of the statute by the Courts of Appeals should not have been biased by the misconception that Congress intended premarket approval to be the maximum protection afforded the public.

Stripped of the policy bias adopted by the Courts of Appeals, the most natural reading of the statute here preempts only state requirements that are targeted at a specific device, such as hearing aid regulations, rather than requirements of general applicability, such as the common law of torts. This conclusion flows from the specific words used in the device preemption provision of the Food, Drug and Cosmetic Act. That provision provides:

> [N]o State...may establish or continue in effect with respect to a device intended for human use any requirement (1) which is different from, or in addition to, any requirement applicable under this chapter to the device....

21 U.S.C. § 360k(a).

Webster's New Collegiate Dictionary defines "respect" as "a relation to or concern with something usually specified" and defines "respecting" as "in view of" and "with regard to."

WEBSTER'S NEW COLLEGIATE DICTIONARY 986 (1977). The common law of torts does not have any specified relationship with "a device," nor was it developed in view of or with regard to "a device." Therefore, if the phrase "with respect to a device" is to be given its plain dictionary meaning, the common law is not a "requirement with respect to a device."

In reaching a contrary interpretation of the scope of preemption, the Courts of Appeals ignored the difference between the phrase "with respect to," used by Congress to describe the state requirements preempted, and the word "applicable," used by Congress to describe the federal requirements that trigger preemption. Webster's defines "applicable" as "capable of or suitable for being applied," and supplies the following example: "There are several statutes applicable to the case." *Id.* at 54. The interpretation of the Courts of Appeals is supportable if one substitutes the phrase "applicable to" for the phrase "with respect to" in the statute. Certainly, the common law of torts is applicable to devices. If Congress had intended to include state requirements that are merely applicable to a device, then it could have used "applicable to" in place of "with respect to," as it did in the clause of the provision describing the federal requirements triggering preemption. Congress's choice to use a narrower phrase to describe the state laws within the scope of preemption than the phrase it used to describe the federal laws triggering preemption should be given effect.

That Congress did not intend preemption of general state laws that have no reference to a medical device is further reinforced by the use of the word "device" in the singular. Had Congress intended to preempt generally applicable state laws, it would more likely have used the phrase "with respect to devices" rather than "with respect to a device." Moreover, the phrase "federal requirement applicable under this chapter to the device" uses the word "the device" to refer back to the device referenced by the preempted state requirement. This reference back to the specific device regulated by state law

makes no sense when applied to the general common law, as the common law makes no reference to any medical device.

In their rush to validate their own policy presumptions, the Courts of Appeals failed to adequately consider the import of the preemption language used by Congress. As evidenced by that language, Congress did not intend to preempt common law tort causes of action.

b. The decisions of the Courts of Appeals conflict with the FDA's preemption regulations and with a recent decision of the Supreme Court of Hawaii.

The decisions of the Courts of Appeals are, as discussed at length in the King Petition at 13-15, inconsistent with the FDA's regulation implementing 21 U.S.C. §360k and with the decision of the Supreme Court of Hawaii in *Larsen v. Pacesetter Systems, Inc.*, 837 P.2d 1273 (Hawaii 1992).

The FDA has determined, as is argued herein, that only state requirements specifically directed at devices are preempted. In adopting its regulations implementing the preemption provision of the statute, it determined that "State or local requirements of general applicability where the purpose of the requirement relates...to other products in addition to devices..." are not preempted. 21 C.F.R. § 808.1(d).

In *Larsen* the Supreme Court of Hawaii determined that premarket approval is not a federal requirement that triggers preemption under the statute. The court reviewed the federal regulations concerning premarket approval and concluded that they merely set forth general procedural requirements which did not trigger preemption analysis under the statute.[6] *Larsen*, at 1282.

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[6] The *Larsen* case, like this case, provides another example of a safety hazard discovered after FDA approval. *Larsen* involved an approved pacemaker that was recalled after it was discovered that it malfunctioned at temperatures slightly above normal body temperature. The plaintiff in Larsen endured several surgeries, including major open heart surgery, and life threatening complications in order to replace his FDA approved pacemaker.

The interpretations of the FDA and the Supreme Court of Hawaii conflict with the interpretations of the Courts of Appeals. This conflict can only be resolved by this Court.

c. The Courts of Appeals analyzed the breach of warranty and fraud claims in these cases in contravention of the principles set forth in this Court's *Cipollone* decision.

Even if this Court were to determine that Congress intended to preempt common law causes of action in this area, the conclusion of the Courts of Appeals that common law actions for fraud, misrepresentation, and breach of warranty are preempted directly conflicts with this Court's holding in *Cipollone*.

The preemption provision at issue in *Cipollone* and the provision at issue here are similar in that both statutes preempt state "requirements." In *Cipollone*, this Court held that the requirements upon which a breach of warranty claim is based are imposed by the manufacturer, not the state, and therefore are not state "requirements." *Cipollone*, at 2633. There is no basis for distinguishing this case. The requirements upon which the breach of warranty claims here are based are imposed by Collagen upon itself, not by the states, and therefore are not preempted state "requirements."

Stamps' and King's fraud and misrepresentation claims should also be found not to be preempted. In *Cipollone*, this Court distinguished between requirements arising out of a duty not to deceive, and requirements arising out of a duty to make such warnings as are necessary to make a product reasonably safe. *Cipollone*, at 2624. The Court held that only the latter class of requirements were preempted because they related to "smoking and health." The Court held that because fraud and misrepresentation claims arose out of a duty not to deceive rather than a duty relating to smoking and health, fraud and misrepresentation claims were not preempted. *Id.*

In this case, only requirements relating to the "safety and efficacy" of a device are preempted. 21 U.S.C. § 360k(a). This

language is essentially the same as that in the Public Health Cigarette Smoking Act, and should be similarly construed to preempt only requirements arising out of a duty to warn of unreasonable safety hazards. Requirements arising out of a generalized duty to be truthful should not be preempted.

In sum, the Courts of Appeals have adopted a novel interpretation of a federal preemption statute. Their interpretation is contrary to the plain language of the statute, conflicts with both FDA and state court interpretations of the statute, and deviates from one of this Court's recent interpretations of a similar statute. Considering the dramatic impact that their interpretation will have upon the rights of persons injured by medical devices and the safety of the medical device using public, this Court should review this case and restore to the States their ability to provide their citizens with tort remedies for injuries caused by dangerous medical devices.

Conclusion

For the foregoing reasons, the Petitions for Writ of Certiorari should be granted.

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No. 92-1979

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IN THE

Supreme Court of the United States

OCTOBER TERM, 1992

JANE KING,

Petitioner,

v.

THE COLLAGEN CORPORATION,

Respondent.

On Petition for a Writ of Certiorari to the United States Court of Appeals for the First Circuit

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In The

Supreme Court of the United States

October Term, 1992

No. 92-1979

JANE KING,

Petitioner,

v.

THE COLLAGEN CORPORATION,

Respondent.

REPLY BRIEF FOR PETITIONER

In this case, the court of appeals held that all state-law damage claims against the manufacturers of FDA-approved Class III medical devices -- the devices most likely to cause serious injuries to consumers -- are preempted by the Medical Device Amendments ("MDA") to the Food, Drug and Cosmetic Act ("FDCA"), 21 U.S.C. § 360c, *et seq.* As a result, victims of those devices, such as petitioner Jane King, are left without *any* remedy for their injuries. This case is worthy of review because the federal and state courts are split over the proper interpretation of the MDA's preemption provision, the court of appeals misinterpreted the authoritative views of the Food and Drug Administration ("FDA"), and the issue presented here is manifestly important. Petitioner has now been joined by twenty-eight states and territories in urging that certiorari be granted. *See* Brief of Alabama, *et al.* (filed Aug. 18, 1993).

In its opposition, respondent argues that there is no division among the lower courts, that the FDA's interpretations support the First Circuit's ruling, and that, even if they do not, they should not be followed. As we show below, respondent misinterprets the relevant legal authorities, overlooks others, and

offers no persuasive reason why review should not be granted.

A. Conflicts With Other Decisions.

Respondent insists that there is no conflict between the decision of the court of appeals below and that of the Hawaii Supreme Court in *Larsen v. Pacesetter Systems, Inc.*, 837 P.2d 1273 (1992). There, a manufacturer argued that the MDA's premarket approval ("PMA") of its Class III device constituted a "requirement" that preempted a damage action under 21 U.S.C. § 360k(a), but the court held that "the statutes and regulations governing pre-market approval set forth general procedural requirements and, therefore, do not trigger preemption analysis under [21 C.F.R.] § 808.1(b)." *Larsen*, 837 P.2d at 1282. As the attorneys general of twenty-eight states and territories, including Hawaii, have recognized, this ruling squarely conflicts with the decision of the court of appeals in this case. *See* Brief of Alabama, *et al.* 16-17 & n.6.

Admittedly, after rejecting preemption on the basis of the PMA requirements, *Larsen* also refused to preempt the plaintiff's claims on the ground that the devices were approved for marketing only under the FDA's truncated "substantial equivalence" procedures. But under the First Circuit's analysis, which tied preemption of all but petitioner's fraud-based claims to the FDA's approval of respondent's labeling (13a, 18a), this secondary holding also irreconcilably conflicts with the decision below, because, even in "substantial equivalence" cases, the FDA considers the manufacturer's proposed labeling. *See* Pet. 13 n.7.

Respondent also misses the mark when it attempts to distinguish the MDA preemption cases involving hearing aids and tampons (*see* Pet. 15-17 & n.10), on the ground that those devices are covered under somewhat different regulatory regimes. The important point for preemption purposes -- which respondent nowhere addresses -- is that in those cases the courts narrowly applied the term "requirement" in 21 U.S.C. § 360k(a), finding preemption only where the FDA's regulations or the MDA itself demanded a specific warning or other regulatory requirement that could not be changed *and* the state was attempting to regulate in that precise area. Here, there are no "requirements" concerning respondent's alleged inadequacies in the manufacture, testing, or design of its collagen implants and, thus, there is no preemption of

petitioner's causes of actions based on those claims.[1] The same analysis applies to petitioner's duty to warn and misbranding claims. Although the FDA passed on the labeling supplied to it by respondent, there is no required regulatory warning for collagen implants and, more importantly, respondent was free to add warnings without prior FDA approval, *see* 21 C.F.R. § 814.39(d), a fact which respondent ignores. *See also* Brief of Alabama, *et al.* 7-8.

Despite respondent's protestations to the contrary (Opp. 9), the court of appeals' ruling runs afoul of this Court's decision in *Cipollone v. Liggett Group, Inc.*, 112 S. Ct. 2608 (1992), which requires the courts to give separate consideration to each claim that is alleged to be preempted. That analysis is directly contrary to the one employed below, which, while purporting to follow *Cipollone*, preempted petitioner's claims because the FDA had passed on respondent's labeling (11a, 13a), even though most of her claims were not based on a duty to warn.

The incompatibility of the First Circuit's decision with *Cipollone* is nowhere more evident than in its treatment of petitioner's fraud and misrepresentation claims, which have no conceivable corollary in any MDA "requirement" or specific PMA condition applicable to respondent's product. Rather, as in *Cipollone*, those claims are not preempted because they are grounded on a general duty not to deceive, not any obligation under the MDA. 112 S.Ct. at 2623-24; *see also* 21 C.F.R. § 808.1(d)(1)(no preemption under MDA where claim relates to general duty applicable to "other products in addition to devices...").

Respondent makes little attempt to defend preemption of petitioner's fraud claims on its merits, but tries to create ambiguity in the court of appeals' decision where none exists. A majority of the panel, Senior Judges Aldrich and Campbell, held that the fraud and misrepresentation claims were preempted (19a-20a), and while

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[1] Although respondent repeatedly asserts that the pre-market approval in this case contained "detailed requirements" for the design of respondent's product (Opp. at 2; *see also id.* at 3, 6), there are no FDA or MDA design requirements of any kind for collagen implants generally, or respondent's product specifically, as evidenced by respondent's failure to cite any authority for its claim.

Judge Tourrella rejected the fraud claim on state-law grounds (11a), he also did so on federal preemption grounds (*id.*), a fact which respondent omits. Thus, it is clear that any claim that a PMA was obtained through fraud is preempted under the law in the First Circuit. That holding, as well as the court of appeals' other preemption rulings, warrant this Court's attention, because of their evident incompatibility with *Cipollone* and decisions of other state and federal courts.[2]

B. The Inapplicability of MDA Preemption to Damage Actions and FDA's Authoritative Views.

The petition also argued that review should be granted because the MDA's preemption provision, 21 U.S.C. § 360k(a), was not intended by Congress to preempt damage claims. Section 360k(a) speaks of a "State or political subdivision of a State ... establish[ing] or continu[ing] in effect" device requirements, which cannot reasonably be construed as referring to a jury's award in a damage action. Nonetheless, respondent relies principally on *Cipollone*, which held that, in some circumstances, the term "requirement" can include a common law duty, 112 S. Ct. at 2619-20, although, as we have explained (Pet. 21-24), *Cipollone* involved a statute whose overall preemption language is very different from that of the MDA.[3]

The question of whether the term covers damage actions depends on its context in the operative statute. Section 360k(a)

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[2] Respondent claims that the Fifth Circuit's decision in *Stamps v. Collagen Corp.*, 984 F.2d 1416 (5th Cir. 1993), *cert. pending*, No. 92-1989 (filed June 16, 1993), finding preemption in another collagen case, evidences "growing unanimity" (Opp. 6), and that, therefore, review should be denied. The foregoing discussion demonstrates that judicial views of MDA preemption are anything but unanimous. We note as well that, in *Cipollone*, this Court granted certiorari even though all the courts of appeals that had considered the issue found all of plaintiffs' claims preempted. 112 S. Ct. at 2613 n.2.

[3] Respondent simply errs in stating that "[e]very lower federal court to have addressed the question since *Cipollone*" (Opp. 7) has concluded that a "requirement" includes common law claims for preemption purposes. *See MacDonald v. Monsanto Co.*, 813 F. Supp. 1258, 1260-61 (E.D. Tex. 1993)("requirement" under preemption provision of Federal Insecticide, Fungicide, and Rodenticide Act does not include common law claims); *Couture v. Dow Chemical U.S.A.*, 804 F. Supp. 1298, 1301-03 (D. Mont. 1992)(same).

uses the word "requirement" several times; in subsections (a)(1) and (a)(2) of 21 U.S.C. § 360k, the statute refers to a "any requirement applicable under this Act," which is a clear reference to statutory and regulatory specifications for devices themselves under the MDA, not to damage remedies. In the introductory paragraph of section 360k(a), referring to the actions of states and their political subdivisions, the term is also used, and there is no reason to believe that Congress meant it to be used differently there. *See Sutherland Statutory Construction* § 47.16, p. 161 (Sands 4th ed. 1984)(multiple uses of same word ought to be accorded same meaning); *see also* Pet. 21 & n.3 (legislative history supports petitioner's interpretation).

It is this use of "requirement" in subsection (b) of § 360k on which the petition also relied (Pet. 23-24). That provision allows the FDA to exempt certain requirements from preemption, and obviously applies only to the legislative and regulatory enactments of state and local governments, not, as respondent asserts (Opp. 13 n.5), to state-law damage claims. Thus, the meaning of "requirement" in subsection (b) strongly indicates that subsection (a)'s preemption language, which uses the same term, is similarly limited. Indeed, the only court to have specifically addressed the question of whether subsection (b), and thus subsection (a), could apply to damage claims, labeled the idea "absurd." *Callan v. G.D. Searle & Co.*, 709 F. Supp. 662, 667 (D. Md. 1989); *see also* Pet. 24 n.16 (citing other relevant cases); *cf.* Brief of Alabama, *et al.* 14.

Finally, respondent misstates the FDA's views on MDA preemption. For the most part, we rely on our initial discussion (Pet. 21-22 & nn. 13-15), which explains that the FDA's regulations, regulatory commentary, and other authoritative pronouncements refer repeatedly to the preemption of certain state and local positive enactments, do not even suggest the possibility of preemption of damage awards, and, indeed, on several occasions, indicate that such awards would not be preempted because they are premised on duties that "relate[] to other products in addition to devices ... ." 21 C.F.R. § 808.1(d)(1).

A few points made by respondent do require a response, however. First, the fact that a "court decision" may be subject to preemption, *see id.* § 808.1(b), is of no consequence. As we have

stated (Pet. 21), a "court decision" interpreting a state regulation, like the regulation itself, could be preempted in some circumstances. This is precisely why, when considering whether to grant an exemption to preemption, or whether there is preemption at all, the FDA requires the states and localities to submit "any statute, rule, regulation or ordinance," along with any "judicial or administrative interpretations [thereof]." *Id.* § 808.20(c)(1); *see also id.* § 808.20(d). In short, the fact that preemption of state and local laws should be considered in conjunction with "court decisions" interpreting them does nothing to undermine the FDA's view that tort claims are not preempted by the MDA.

Second, respondent sidesteps the importance of the FDA's rule that preemption applies only to state and local requirements that are specifically about devices, not general legal duties, 21 C.F.R. § 808.1(d)(1), by stating that this is only true when those duties do not apply to substantive requirements applicable to devices. Opp. 12 n.8. This makes no sense, because if a damage action alleging warranty claims under the Uniform Commercial Code, or a fraud claim under a state unfair trade practice act, *see* 21 C.F.R. § 808.1(d)(1), does not involve a substantive requirement applicable to a device, it could not possibly be preempted and FDA would not have to say so. *See* Pet. 15 n.8. The clear purpose of § 808.1(d)(1) is to limit preemption to state and local requirements that apply *only* to devices, not to general duties imposed by state law that apply to devices as well as other products.

Finally, respondent ends its discussion of the FDA's views with citations to regulatory commentary which, it implies, supports the view that pre-market approval of a Class III device, standing alone, preempts all state law concerning those devices, including damage claims (Opp. 8-9). However, that commentary stands for an entirely different proposition: once FDA requires pre-market approval of a specific device, state or local governments may be precluded from enforcing their own PMA procedures as to that device. Indeed, the commentary strongly indicates that MDA preemption applies in a quite limited way and only to the regulatory programs of the states, not to damage claims. *See* 45 Fed. Reg. 67321, 67323, col. 1 (Oct. 10, 1980); 43 Fed. Reg. 18661, 18664, col. 1 (May 2, 1978).

C. The Manifest Importance of the Decision Below.

Respondent does not dispute the importance of the decision below, other than to suggest that some consumers injured by Class III medical devices might have recourse against persons other than manufacturers, such as doctors. Respondent also asserts that consumers may have state-law claims for violation of the FDCA (Opp. 14 n.10, *but see* Opp. 9 n.5), which is ironic here because petitioner *did* argue that respondent's device was misbranded within the meaning of the FDCA, and the court of appeals held that claim preempted also (10a, *citing* 21 U.S.C. § 352(a)(FDCA misbranding)).

Respondent does not even attempt to explain away the view of the former FDA Chief Counsel that this case is "probably the single most important case to the medical-device industry in American history." *See* Pet. 3.[4] Now that twenty-eight states and territories have taken the rare step of filing a brief in this purely private case, urging the Court to grant the petition, there can be little doubt that this case is of great concern not only to American consumers, but to their governmental protectors, largely because it will leave victims with no remedy at all. *Compare, e.g., English v. General Electric Co.*, 496 U.S. 72, 87-90 (1990)(presumption against preemption especially weighty where Congress has not provided judicial recourse); *Silkwood v. Kerr-McGee Corp.*, 464 U.S. 238, 251 (1984)(same).

Conclusion

The petition for writ of certiorari should be granted.

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[4] *See also, e.g.*, Linda Himmelstein, *An Invincible Shield for Medical Manufacturers -- The Courts May Ban Lawsuits Over Devices Approved by the FDA*, Business Week, Aug. 9, 1993, at 73.

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